The Medical Device Market and Its Industrial Evolution in China

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Declaration

I hereby declare that this thesis has not been and will not be, submitted in whole or in part to another University for the award of any other degree.

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University of Sussex

Thesis Submitted in Fulfilment of the Requirements for the Degree of

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By: Weifan Zhang

Summary

China has attracted increasing amounts of foreign investment since it opened its doors to the world and whilst many researchers have focused on foreign investment in popular areas, little has been written about medical device market. The medical device market is one of the most profitable areas in the global economy. With the development of China's economy, the Chinese medical device market is experiencing significant growth, and has become the second largest market in the world.

The research in this thesis extracted foreign direct investment theory and summarized the current situation of the global medical device market and the Chinese medical device market. Analysis of the status of the Chinese medical device market from the perspective of the healthcare industry and its important market drivers, reveals that the medical device market has significant growth potential.

The research methods such as: regression analysis; location quotient, which revealed the Chinese medical device market status, provides suggestions for investors who are interested in entering the Chinese market. Investors or companies who want to enter the Chinese market need to understand the regulatory environment, comparison of the medical device regulations with the US and EU regulations provide investors with a clear understanding of the Chinese medical device regulatory regime.

The research in this thesis contributes to medical device market investment and regional economy in medical device industry, and make a clear statement of the changing medical device regulations in China, which came into force on 2014. The contribution of this thesis, bridges the research gap between investment theory and medical device market development.

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List of Publications

1. **Weifan Zhang**, Rebecca Liu and Chris Chatwin, *Investment guidance for the Chinese medical device market.* Journal of Medical Marketing (2015). DOI: 10.1177/1745790415605414
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3. **Weifan Zhang**, Rebecca Liu and Chris Chatwin, *The medical device market: market drivers and investment prospects*. Journal of Commercial Biotechnology (2016) 22(2). Pp27-33. DOI: 10.5912/jcb741

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List of Abbreviations

CAMDI	China Association for Medical Devices Industry
CAME	China Association of Medical Equipment
CCC	China Compulsory Certification
CCCMHPIE	China Chamber of Commerce for Import & Export of Medicines & Health Products
CFDA	China Food and Drug Administration
CHA	China Hospital Association
CT	computed tomography
EIT	electrical impedance tomography
EU	European Union
EUDAMED	European Databank on Medical Devices
FDA	Food and Drug Administration
FDI	foreign direct investment
GCP	good clinical practices
GDP	gross domestic product
GHTF	Global Harmonization Task Force
GMP	good manufacturing practice
HDE	humanitarian device exemption
HUD	humanitarian use device
IDE	investigational device exemption
IDP	investment development path
IMF	International Monetary Fund
ISO	International Organization for Standardization
IT	information technology
IVD	in vitro diagnostic
LQ	location quotient
M&A	mergers and acquisitions
MDD	Medical Device Directive
MNC	multinational company
MRI	magnetic resonance imaging
MS	market share

NOI	net outward investment
NPV	net present value
PLC	product life cycle
PMA	premarket approval
QS	quality system
R&D	research and development
UN	United Nations
WHO	World Health Organization
WTO	World Trade Organization

List of Symbols

Y:	dependent variable
x:	independent/explanatory variable(s)
β:	unknown parameter(s)
$\widehat{\beta}_i$:	parameter estimator(s) of β_i
μ:	the stochastic disturbance term/error term
Y_i:	linear combination
$\widehat{Y}_i$:	estimator of Y_i
i:	ith observation
$\bar{R}^2$:	adjusted R
t:	t value
β_1^*:	hypothesized numerical value of β_1
$\|t\|$:	the absolute value of t
t_α or $t_{\alpha/2}$:	the critical t value at the α or $\alpha/2$ level of significance
df:	degrees of freedom
E_{ij}:	economic activity in area/region i industry j
E_i:	total economic activity in area/region i
$\sum_i E_{ij}$:	economic activity of industry j in the whole area/region
$\sum_i E_i$:	total economic activity in the whole area/region

Chapter 1 Introduction

1.1 Research background

The economy in China has experienced 30-years of rapid growth and obtained remarkable success ever since the great reforms and opening-up policy. This reform in China represents a fundamental change and overhaul of China's value system; policy making; institutional infrastructure and socio-economic structure, which constitutes a necessary step for mobilizing foreign investment. As an emerging market, China offers long-term growth opportunities that no longer exists in relatively saturated and highly competitive developed markets [1]. China has substantial size and a high growth rate of its consumer market, this is the reason why China is attractive to foreign investors [2].

As a high-tech intensive industry, the medical device market is one of the fastest growing industries in the world. The medical device industry indicates the level of a country's manufacturing and technology sector. The Chinese government is encouraging the development of the medical device industry. The size of the medical device market continues to exhibit a rapid growth trend in China, the growth rate recently reaching 23%, the total output value reached approximately 688,420 million yuan (RMB) in 2011 [3].

1.2 Aims and objectives

The diagnostics market is segmented broadly into the *in vivo* diagnostics market (*in vivo* means within a living organism) and *in vitro* diagnostics (IVD) market (*in vitro* means in the laboratory or outside the organism). *In vivo* diagnostics is a specialty market, with the key players being large instrument manufacturers of imaging or instrumentation technology (GE, Siemens and Philips, etc.). Examples of these devices are CT, MRI ultrasound and X-ray. There are two types of IVD products: devices (analysers for samples like blood, serum, tissue, bodily fluids, etc.) and reagents (chemicals used to mark or recognize specific components in the samples) [4].

This thesis will focus mainly on the *in vivo* diagnostics market. The demand for the new technology diagnostic devices has been growing in both developed and developing countries in recent years. As a developing country, it is important to know whether the

Chinese medical device market offers an attractive investment opportunity, when compared with other industries. One powerful development supporting a positive hypothesis is that people are paying more attention to their health due to the improved quality of life. Another is that treatment of some serious diseases requires high quality medical devices. Moreover, the aging population is a big challenge for the Chinese market.

This thesis aims to explore the potential of the investment opportunities in the Chinese medical device market. The purpose of this thesis is: (1) extracted foreign investment theory in healthcare or high-tech areas; (2) evaluate the global medical device market status and illustrate the Chinese medical device market from the perspective of time lines, comparison analysis of the market's past and present, to show that the market has improved greatly; (3) understand the main rapidly growing Chinese medical device market drivers; (4) understand medical device regulations in the United States (US), European Union (EU) and China, summarize the difference between these regulations; (5) identify which are the best investment regions in China.

The objectives of the research is to provide a background on the Chinese healthcare system, reforms and changing regulatory environment to describe the current situation of the Chinese medical device market and to define opportunities for foreign investment potential therein.

1.3 Contributions

Although there is growing interest in investment in China, analysis of the medical device area has been slow to develop, but the sector is growing in importance with the improved realization that investment in the medical technology area, especially medical device, produces exceptional value. Some reports provide valuable information on the Chinese medical device market and investment environment, but they are limited in comparison with a literature review. Literature on investment in medical device technology and market is scarce, this research contributes to the literature on both investment and the medical device market. It extracts technology investment theories from foreign investment theories. The research demonstrates that the medical device market has become a promising global market, especially since the Chinese government pays more attention to healthcare than before, relevant policies on medical device investment will

be helpful to investors doing business in this area. More and more business research will focus on the medical device investment area in the future. Moreover, few papers focus on investment in the medical device market, with little attention focused on the medical device regulations, especially the new Chinese medical device regulations, which came into force on 2014.

To bridge the gap, this thesis reveals the main drivers of the Chinese medical device market, to determine the viability of investment and provides some insights into the future investment opportunities in the Chinese medical device market. Comparison of the old and new medical device regulations, provides important updated information of the changing regulatory environment for the investors who are interested in entering the Chinese medical device market. For the first time the location quotient is introduced into the analysis of the medical device industry, the results indicate that the best investment regions in China are: Bohai Economic Rim, Yangtze River Delta and Pearl River Delta Economic Zones. This thesis contains extensive data relevant to the medical device industry, illustrating that the Chinese medical device market is one of the most promising markets globally.

1.4 Thesis outline

The thesis consists of 8 chapters, which are organized as follows:

Chapter 1 briefly outlines the research background, research aims and objectives and research contributions made to the knowledge of the medical device market.

Chapter 2 introduces foreign direct investment in healthcare or high-tech development areas for both developed countries and developing countries. It extracts foreign direct investment theory in medical device industry.

Chapter 3 presents the global medical device market size and main medical device companies, especially medical imaging companies and their market share of medical imaging devices. It shows the key players in the medical imaging market.

Chapter 4 reviews China's current economic situation and the Chinese medical device market from an economic perspective; identifies important parameters controlling this market. Regression analysis shows that the main drivers of the Chinese medical device market are the number of hospital visits, aging population and the number of hospitals. Analysis of the main market drivers, illustrates that the Chinese medical device market offers significant investment opportunities.

Chapter 5 summarizes the US and EU medical device regulations, because they have established relatively mature regulations, which have a key influence in the world. Compared with the relatively mature regulations, the Chinese medical device regulations is evolving. The new regulations, which came into force on 2014, was a milestone in the Chinese medical device regulations history. The thesis outlines the changing regulatory regime, which provides guidance for the investors who are interested in entering the Chinese market.

Chapter 6 introduces location quotient method to assess which area is the best region for medical device investment in China. The location quotient and market share matrix reveals that the best investment regions are the: Bohai Economic Rim, Yangtze River Delta and Pearl River Delta Economic Zones. It was the first time that the location quotient method has been introduced into the medical device market study, which provides guidance for the study of medical device market in other countries or regions.

Chapter 7 is an extension of Chapter 6, it provides SWOT analysis of the Chinese medical device market and analysis of the Chinese regional market competitiveness. According to Chapter 6's results, the best investment regions in medical device industry are: Bohai Economic Rim, Yangtze River Delta and Pearl River Delta Economic Zones. However, each region has its own characteristics and advantages. The detailed analysis provides useful information for the investors.

Chapter 8 is the conclusion of this thesis and gives some suggestions for the future work.

Chapter 2 Literature Review

2.1 Foreign investment theories for the developed countries

From 1960s, with the rapid development of foreign direct investment (FDI) from advanced developed countries, researchers began to study multinational companies' (MNCs) investments from different angles and at different levels in order to illustrate the motivations and determinants of FDI. Some of the famous theories for FDI have come into being from that time.

The medical device market has been relatively unaffected by globalization directly before, but it plays more and more important role in the global market. Therefore, it is important to summarise the literature in the area of health products or the health products industry.

2.1.1 Monopolistic advantages theory

Hymer [5] developed a microeconomic explanation of direct investment and tests it against miscellaneous facts. The main motivation of a company with international production is to fully use its various advantages, such as: advanced technology, perfect marketing system and strong management capabilities. Hymer proposes two basic lines of explanation as to why a company in one country should assume control over a company located in another. Firstly, foreign investment can comprise a strategic move in an oligopolistic market, with horizontal FDI[1] serving to extinguish competition among rivals and vertical FDI[2] to avoid the reefs of bilateral monopoly. Secondly, FDI can allow the company to make profitable use of some strategic advantage in factor costs, production efficiency, distribution system, or product differentiation.

Kindleberger has promulgated Hymer's opinions later. They developed the monopolistic advantages theory to explain the motivation for control in FDI. They assume that a foreign subsidiary has certain disadvantages compared to a domestic company, which are called the "liabilities of foreignness". These disadvantages are: (1) less local knowledge of law,

[1] Horizontal FDI means a company establish factories or value chain in several countries to duplicate its home country-based activities.
[2] Vertical FDI means a company establish factories to produce raw materials in order to supply the parent company itself or its subsidiaries.

economy, society, culture and language leading to higher information costs and risk; (2) foreign companies often face discriminating regulations from government regarding taxation or employment; (3) the transfer of earnings are exposed to exchange rate risk; (4) the geographical distance between parent company and subsidiary leads to communication and coordination costs. In Hymer's opinion, a company needs to realize monopolistic advantages, which are based on defective markets if a company wants to overcome these "liabilities of foreignness". These advantages are: (1) financial advantages: in general, MNCs have strong financial strength and a high degree of credibility, which makes it easy to obtain loans from the international financial institutions; (2) technical advantages: MNCs have strong research teams and have the ability to invest in research and development (R&D) of new technologies and new products; (3) information and management advantages: MNCs' subsidiaries located in different countries, unify management and global integration strategic principles, which brought them together, to exchange ideas so that makes their action unified; (4) credibility and trademark advantages: MNCs' important intangible assets are also an important aspect of their monopolistic advantages. MNCs can use their reputation to consolidate the existing markets and develop the new markets; (5) economies of scale advantage: MNCs always expand their scale to reduce product cost and increase profits; use the international distribution channels to sell products in large quantities at low costs globally.

Michael Klug [6] said, a criticism of this monopoly theory is that it only partially explains FDI. A firm's motivations when investing overseas are to exploit existing advantages abroad and aim for additional advantages such as the access to know-how or resources. Another aspect of criticism is that the monopolistic theory explains why companies exist in foreign markets but does not explain why a subsidiary is more profitable than exporting.

In summary, Hymer argued that a foreign investor possesses some kind of proprietary or monopolistic advantages, which are not available to local firms. These advantages must be economies of scale, superior technology, or superior knowledge in marketing, management, or finance. FDI took place because of the product and factor market imperfections. Hymer's opinion gave us the theoretical analysis of foreign investment as optimization by the company, of the association between investment and the elements of market structure have made great strides. However, monopolistic advantages theory also has some shortcomings. For instance, the subject of his research is only the powerful

American MNCs, which have monopolistic advantages in particular business areas. According to Hymer's theory, the companies cannot do FDI if they do not have monopolistic advantages in the business areas. Since the 1980s, with the development of FDI from developing countries' MNCs, this theory has been challenged.

2.1.2 Product life cycle

Vernon [7] presented the theory of product life cycle and suggested that a company has to use FDI in order to occupy the foreign market in 1966. In Vernon's opinion, the entrepreneur's consciousness of and responsiveness to opportunity are a function of ease of communication; and further, that ease of communication is a function of geographical proximity. Producers in any market are more likely to be aware of the possibility of introducing new products in that market than producers located elsewhere would be.

A product life cycle (PLC) refers to the time period between the launch of a new product into the market till it is finally outdated. This cycle is split into four different stages which encompass the product's journey from its entry to exit from the market. The four different stages are: introduction stage; growth stage; maturity stage and decline stage. Vernon defined PLC as location of new products; the maturing product and the standardized product.

Location of new products

In this stage of introduction of a new product, producers were usually confronted with a number of critical conditions. The product itself may be unstandardized for a time. The unstandardized nature of the design at this stage carries with it a number of locational implications. (1) Producers at this stage are concerned with the degree of freedom they have in changing their inputs and the costs of the inputs as well. (2) The price elasticity of demand for the output of individual companies is comparatively low; the companies can get the monopoly advantages in this stage. (3) The need for swift and effective communication on the part of the producer with customers, suppliers, and even competitors is particularly high at this stage. In summary, at the introduction stage, the producers who find a market for some new product in their own countries may be led to select a location for production in their own countries on the basis of national locational considerations, which extend well beyond simple factor cost analysis plus transport costs.

When products pass through the introduction stage, the sales of products succeed, we can say the products enter into the growth stage. Consumers accepted the products. So the company has managed to get consumers attention and now works on increasing their product's market share. The cost of production declines, rapid sales and profits are characteristic of this stage.

The maturing product

This stage is the most competitive as different companies struggle to maintain their respective market share. In this stage, (1) the need for flexibility declines; (2) concern about production cost begins to take the place of concern about product characteristics. In this stage, the producers will consider whether setting up a new production facility in other countries. With American producers for example, if the marginal production cost plus the transport cost of the goods exported from US is lower than the average cost of prospective production in the market of import, the US producers will prefer to avoid an investment. However, the locational force, which determined some particular overseas investment is so easy and so powerful that one has little difficulty in identifying it. From Vernon's opinion, the US producers have established production units in the advanced countries. To compare with a US producing facility and an advanced country producing facility, the obvious production-cost differences between the rival producing areas are usually differences due to scale and differences due to labour costs. If the market is being fully exploited, the principal differences between any two locations are likely to be labour costs. According, the company will begin servicing developing countries markets from a new location.

The standardized product

In this stage, the standardization of some products, the less-developed countries may offer competitive advantages as a production location due to the relatively low labour costs, which impact labour-intensive products. The producers are looking for a low-cost captive source of supply. The competition between companies will be mainly the competition for the price of products. At this time, companies may prefer FDI to transfer the production to the less-developed countries, which have low-cost labour.

When developed countries want to increase export business, they transfer technology and investment abroad. It reveals that the FDI motivation and foundations; not only depends

on the special advantages companies have, but also depends on the companies' location advantages in the host country. PLC shows that the world economic integration to some extent and explains the motivation for companies doing business abroad. And it also demonstrates the necessity for companies to invest abroad, both for internal and external reasons. It is considered defensive because competitors are investing to avoid losing the markets served by exports when their initial investor begins local production. They may also fear that the initiator will achieve some advantage of risk diversification that they will have unless they also enter the market. However, the theory of PLC mainly focuses on the production markets, the explanation of resources and technology exploitation in other countries is not enough.

Michael Porter [8] expanded the concepts of PLC in the industry evolution in 1980. Porter illustrated that an industry goes through its life cycle with four stages: introduction, growth, maturity and decline. Moreover, Porter summarized the common predictions about how an industry will change over the life cycle and how this should affect strategy, which is shown in Table 2-1.

Table 2-1 Predictions of PLC. Theories about strategy, competition and performance.

	Introduction	*Growth*	*Maturity*	*Decline*
Buyers and Buyer Behaviour	1, High income buyer 2, Buyers must be persuaded to try the product	1, Buyer group expansion 2, Buyer will accept uneven quality	1, Mass market 2, Saturation 3, Repeat buying 4, Choosing among brands	Buyers are the mastered buyers of the product
Products and Product Change	1, Poor quality 2, Product design and development key 3, Many different product variations 4, Frequent design changes 5, Basic product design	1, Products have technical and performance differentiation 2, Reliability is important for the complex products 3, Good quality	1, superior quality 2, Less product differentiation 3, Standardization 4, Less rapid product changes	1, Little product differentiation 2, Spotty product quality

Marketing	1, Very high advertising 2, High market costs	1, High advertising 2, Advertising and distribution key for nontechnical products	1, Market segmentation 2, Efforts to extend life cycle 3, Service and deals more prevalent 4, Advertising competition	Low advertising and other marketing
Manufacturing and Distribution	1, Overcapacity 2, Short production runs 3, High skill-labour content 4, High production costs 5, Specialized distribution channels	1, Undercapacity 2, Shift toward mass production 3, Scramble for distribution 4, Mass distribution channels	1, Optimum capacity 2, Increasing stability of manufacturing process 3, Lower labour skills 4, Long production runs with stable techniques 5, Distribution channels pare down their lines to improve their margins 6, Mass distribution channels	1, Substantial overcapacity 2, Mass production 3, Specialty distribution channels
R&D	Changing production techniques	---	---	---
Foreign Trade	Some exports	1, Significant exports 2, Few imports	1, Decreasing exports 2, Significant imports	1, No exports 2, Significant imports
Overall Strategy	1, Best period to rise market share 2, R&D, engineering are key functions	1, Practical to change price or quality image 2, Key function is marketing	1, Bad time to rise market share 2, Bad time to change price image or quality image	Cost control is the key

			3, Marketing effectiveness is the key	
Competition	Few Companies	1, Many competitors 2, Many mergers and acquisitions (M&A)	1, Price competition 2, Shakeout 3, Increase in private brands	1, Exits 2, Fewer competitors
Risk	High risk	Risk can be taken here because growth covers them up	Risk cyclicity	---
Margins and Profits	1, High margins and prices 2, Low profits	1, Highest profits 2, Fairly high prices 3, Good acquisition climate	1, Lower margins and profits 2, Decreasing prices 3, Increased stability of market shares and price structure 4, Poor acquisition climate	1, Low margins and prices 2, Falling prices

Hill and Jones [9] introduced industry life cycle model for analysing the effect of industrial evolution. The model has five industry environments, each linked to a distinct stage of an industry's evolution: (1) an embryonic industry environment, (2) a growth industry environment, (3) a shakeout environment, (4) a mature industry environment, and (5) a declining industry environment. Table 2-2 summarized the characteristics of each stage. Industry life cycle model is a generalization. In some cases, industries do not always follow the pattern.

Table 2-2 Stages of the industry life cycle.

Stage	Industrial Characteristics				
	Product Prices	Distribution Channels	Barriers to Entry	Competition Methods	Competition

Embryonic Industries	High	Poor	Access to key technological know-how	Educating customers; Opening up distribution channels; Perfecting product design	Lack of rivalry, suggests build up a strong hold on the market
Growth Industries	Fall	Develop	Technological knowledge as a barrier to entry has diminished	Expand revenues and profits due to rapid growth in demand	Rivalry tends to be relatively low
Industry Shakeout	Price war (Cut prices)	Saturation	---	Continue to add capacity at rates consistent with past growth	Rivalry between companies becomes intense
Mature Industries	Price-leadership agreements; most industries have consolidated and become oligopolies.	Totally saturated	Barriers to entry increase (because brand loyalty and low-cost operations constitute a barrier to entry) and the threat of entry from potential competitors decreases	Cost minimization and building brand loyalty	Reduce the threat of intense rivalry, allowing greater profitability
Declining Industries	Price war (Cut prices)	---	---	Companies begin to cut prices, thus sparking a price war	Companies gradually exit; the degree of rivalry usually increases

2.1.3 Eclectic theory of international production

Eclectic Theory of International Production was presented by John Dunning in 1977 [10] and refined by him several times since then (1988, 1993). Dunning's proposed model was preceded by Hymer's [5] application of industrial organization economics to the study of international trade and investment, and Vernon's [7] definition of an international product life cycle, both critical steps for international business studies away from macro-economic trade theory. Dunning's Eclectic Model, is a key contribution to the separation of international business studies from international economics and trade theory and to the development of global strategy [11]. Dunning expanding the internalization theory, states that the incentives to internalize activities are to avoid the disadvantages, of imperfections on external (markets and public) mechanisms of resource allocation. The eclectic theory has been further elaborated by Dunning in 1981 [12]. The eclectic theory pulled together the ownership advantages, location advantages and internalization advantages, which is also known as the OLI Paradigm. The OLI Paradigm [10, 13] is an attempt to create a framework to explain why MNCs choose FDI to serve foreign markets, MNCs decisions on FDI strategy is based on three essential factors:

(1) "O"— Ownership (or owner-specific) advantages are necessary so that a foreign company has some competitive advantage in the host market [6]. As Dunning [14] describes, ownership factors are unique competitive or monopolistic advantages, typically developed in the home market, that permit the company to complete successfully in overseas markets. These factors are of two types: asset advantages arise from proprietary ownership of unique assets protected by structural market distortions; transactional advantages provide a unique capacity to capture value from the transactional benefits of owning a network of assets located in different countries.

(2) "L"— Location (or location-specific) advantages. These factors are comparative advantages that attract FDI to particular locations. These factors might include a low-cost but productive labour force, local image, unique sources of raw materials or trade barriers, which can be combined with transferable intermediate ownership assets to generate superior products.

(3) "I"— Internalization advantages. The key ingredient for maintaining a firm-specific competitive advantage is possession of proprietary information and control of the human capital that can generate new information through expertise in research [15]. A company needs to realize advantages by internalizing the transaction. Internalization factors, typically related to the industry, produce transactional market failure in transferring ownership advantages to foreign markets [11].

The eclectic theory proposes that only when all three factors (ownership advantages, location advantages and internalization advantages) are favourable will international production take place. These factors can be transferred into Figure 2-1. The eclectic theory discussed the influence of these three factors for the MNCs' international production. Different combinations of these three factors determine the different ways that MNCs participate in international economic activities, which creates a different form of market entry:

Ownership advantages = Licensing

Ownership advantages + Internalization advantages = Export

Ownership advantages + Internalization advantages + Location advantages = FDI

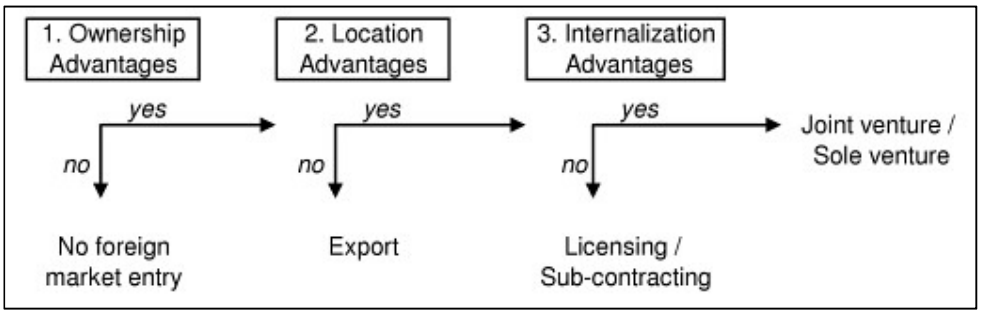

Figure 2-1 The eclectic paradigm and a company's entry choice.

Source: adapted from Hoeck (2008) in reference to Welge and holtbrügge (2003) [16]

Eclectic theory of international production combines a comprehensive theory of MNCs in order to research the motivations and determinants of FDI; it had been regarded as a perfect FDI theory. This theory indicated that MNCs have entered a relatively mature and stable investment stage. However, the research target of this theory is still advanced developed countries' MNCs. Some of the ideas of FDI are absolute. According to this theory, only when all three factors are favourable will international production take place,

but for some developing countries' MNCs, which still do not have all the three factors conditions, this theory cannot explain the international business which is made by some developing countries' MNCs.

2.2 Foreign investment theories for the developing countries

The traditional FDI theory emphasizes that MNCs need to have monopolistic advantages if MNCs want to do business abroad. However, with the development of the global economy, more and more companies from developing countries invest abroad, traditional FDI theory is thus being challenged. Compared with advanced developed countries' MNCs, MNCs from developing countries have no monopolistic advantages, but they still do business abroad even in some advanced developed countries. Therefore, FDI theories for developing countries improved traditional FDI theory and made the theory of FDI more comprehensive.

2.2.1 Theory of small-scale technology

Louis Wells [17] proposed the theory of small-scale technology in his book-- <Third World Multinationals: the rise of foreign investment from developing countries> in 1983. In Wells' opinion, MNCs from the developing countries have three main competitive advantages:

(1) Small-scale technology from developing countries has the feature that it is labour-intensive and flexible, especially suitable for small batch production and can meet the other developing countries relatively narrow market needs. Low-income countries have a common characteristic that the commodity market demand is limited. It is hard for mass production technology to get profits from this small market demand, so, many developing countries are developing the production technology to meet the needs of a small demand market. In other words, they have competitive advantages.

(2) Produce national product in overseas countries. Developing countries' foreign investment always served their own customers' needs in a foreign country. According to Wells (1983), some countries such as India, Thailand, Singapore, Malaysia and China always produce their national products to meet their customers' needs in a foreign country.

(3) The marketing strategy of low-price products. Compared with the advanced developed countries, MNCs' products from developing countries have some competitive advantages: low production costs, cheap labour costs, low advertising costs. All of these competitive advantages will deliver a good position in market share.

The main motivations of MNCs from developing countries investing abroad are: to protect the export markets. Due to the trade barriers, export is not a long-term international business mode, capital exports enable protection of most of their markets. Other motivations for FDI are: looking for low cost, spread their assets.

The feature of the theory of small-scale technology is that it abandoned the traditional ideas of MNCs have to rely on monopolistic advantages succeed with their international economic activities, it combines the developing countries MNCs' competitive advantages with these developing countries' own market features together. It is useful to analyse how the developing countries' MNCs got a good position in the world market in the early stages of internationalization. According to the small-scale technology theory, MNCs can take part in the world business even the developing countries' MNCs which have less technology, small scope of business and the small scale of production through FDI. It is quite meaningful for the developing countries' MNCs to invest abroad. However, Wells inherited Vernon's [7] product life cycle theory; he considered that products produced by developing countries are mainly from advanced developed countries' mature products. Furthermore, this theory cannot explain some foreign investment from developing countries' high technology companies and it cannot explain the growing phenomenon of FDI from developing countries into developed countries.

The theory of small-scale technology is useful, "the spread of foreign investors from developing countries is, in net, beneficial to the development process and to international relations." [17]

2.2.2 State of localized technological capacities (Technical localization theory)

Lall [18] studied how developing countries could gain competitive advantages in the global market. The technical localization theory suggests that the formation of technology

in developing countries contains internal company innovation activities that become its competitive advantages. [19] The developing countries' MNCs have their own specific advantages due to: (1) developing countries' technologies and products linked to their price elements and quality; (2) the products applicable to their own economic conditions and needs, which means companies transform technologies and products they imported, making the products meet the market demand, this kind of innovative activity creates competitive advantages; (3) in the small-scale production conditions, technologies arising from innovation activities have a higher economic efficiency; (4) in a large domestic market, when consumers' purchasing power is very different, the products from developing countries have some competitive advantages.

The technical localization theory is emphasis on imported technology regeneration, which means developing countries' MNCs transformation of imported technology and products is not a passive imitation and replication, but is the process of technology digestion and innovation so that their products can better meet the needs of their local markets. These innovation activities bring competitive advantages to their MNCs.

2.2.3 Technological innovation and industrial upgrading theory

Since the middle of 1980s, the accelerated growth trend appears in the FDI of developing countries, especially some newly industrialized countries and regions, who invest in developed countries, and become the local companies' strong rivals. The challenge for traditional foreign investment theory is how to explain the new investment trend from developing countries.

John Cantwell and Tolentino [20-22] brought "technology innovation & industry upgrade" to the FDI theory. They highlight that (1) the upgrading of the industrial infrastructure of developing countries tells us that developing countries' MNCs technological capabilities as to improved and expanded, the stable technical ability enhancement is a result of continuous accumulation. (2) there is a positive relationship between developing countries' MNCs technological capabilities and their FDI, which means technological capabilities enhancement will bring FDI growth.

Technology innovation is the fundamental driving force of the industry and company development, which promotes national economic development. Compared with the developed countries, which have a large number of R&D investments, developing countries do not have strong R&D capabilities in technology innovation, they use their unique learning experiences and organizational skills to develop the existing technologies.

This theory is based on technology accumulation for inner motivation and on the basis of geographical extension. With the development of technology accumulation, developing countries' MNCs FDI transfer gradually from resource-dependent to technology dependent. Moreover, as FDI industries have escalated, their structure and regional distribution is closely related. Developing countries MNCs' geographic expansion was largely affected by the "psychological distance", which followed the development trajectory of neighbouring countries→ developing countries→ developed countries.

This theory explained the structure of FDI from developing countries especially newly industrialized countries; this structural change is from developing countries to advanced developed countries, and this change is from the traditional industries to the high technology industry. Therefore, this theory is meaningful because it highlights that the developing countries strengthen their technological innovation and technology accumulation through the FDI in order to upgrade their industrial infrastructure and increase international competitiveness.

2.2.4 The theory of investment development cycle

In the 1970s, Dunning tried to use the eclectic theory of international production to seek a generally applicable FDI theory framework. However, this theory is mainly based on the behaviour of FDI of developed countries, the explanatory power of developing countries' FDI is poor. Therefore, Dunning [23] introduced the theory of the investment development cycle in order to further explain the eclectic theory of international production in the 1980s.

The investment development path (IDP) theory hypotheses, illustrated from Dunning, that there is a relationship between the countries' FDI and their level of economic development. Dunning and Narula [24] have used gross domestic product (GDP) as an

indicator of the countries' economic development level. According to the eclectic theory of international production, the dynamic relationship between economic development and net outward investment (NOI) position is attributed to the changes of ownership, location and internalization (OLI) advantages [14]. According to IDP theory, the OLI dynamic interaction can be categorized in five stages, which may be observed in most countries (see Figure 2-2). Stage 1: characterizes pre-industrial societies where weak local demand and inadequate infrastructure limit the attractiveness of the country to foreign investors, while domestic companies lack the requisite O or L advantages. Stage 2: Inward FDI increases significantly in this stage due to the development of some L advantages that raise the countries' attractiveness to MNCs. The O advantages of domestic companies are poor and this limits their outward FDI. To the extent that firms do invest abroad, it is in response to the local government's support, for example in response to subsidies granted for export supporting investment and or capital allocation for resource acquisition [14]. During this stage, the NOI position of the country is negative and has a declining trend. Stage 3: A gradual decline in the rate of inward FDI due to the growing competitiveness of local companies, leads to the increase of the outward FDI. The rate of outward FDI may surpass inward FDI flows. Local companies increase their outward FDI due to the improvement of O advantages. A country's NOI is still negative but is on an upward trend. Stage 4: The rate of outward FDI increases faster than the rate of inward FDI and a country's NOI is positive due to the development of indigenous companies' O advantages, which allows them to not only to complete locally with foreign companies but also to expand their activities abroad. Stage 5: A country's NOI is still positive but fluctuates around zero at this stage. According to Dunning [25], most advanced countries such as the United States, United Kingdom and Japan, their NOI position tends to about zero. There are two key features of this stage [26]: <1> A tendency for companies to internalize cross-boarder transactions through MNCs activity; <2> As economies become more similar in the structures of their location bound assets, their FDI positions are likely to become more evenly balanced.

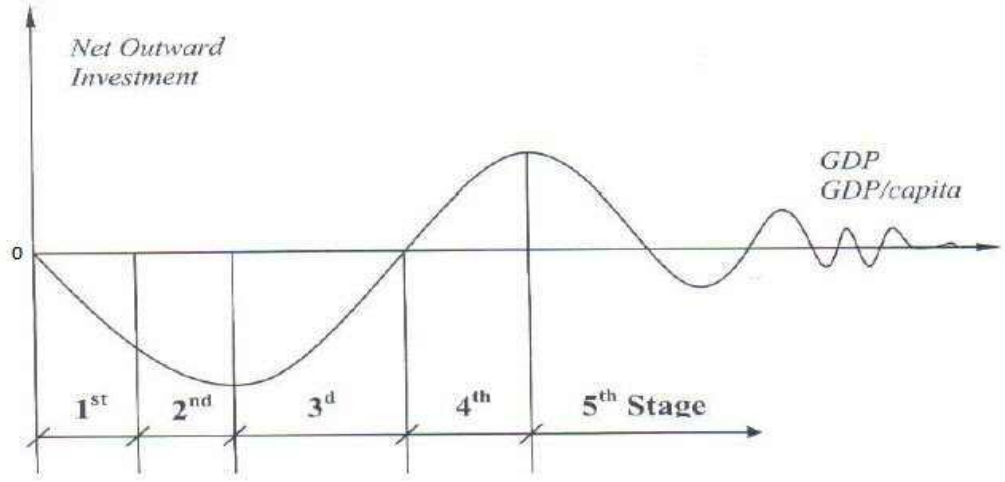

Figure 2-2 The Pattern of the Investment Development Path (IDP).

Source: Dunning and Narula (1996)

Dunning [23] tested the IDP theory by using data of 67 countries for the period 1967-1975. The theory of the IDP shows that the countries which have good economic strength and advanced productive forces are always the countries with abundant capital output and the most active with FDI. However, nowadays not only the scales of advanced countries' FDI expands unceasingly, but also many developing countries' FDI are very active.

2.3 Foreign investment theories for the medical device industry

Whilst there is some literature on the medical device industry and technology investment, it is narrowly focused and more general investment data is scarce. While economic cycles and uncertainties have affected several global industries in the last few years, the medical device industry has gained from the benefits of earlier investments and delivered incomparable improvements in the quality of people's lives in the developed countries [27]. It is on the measure of profitability that the medical device industry truly stands out, as it has a more consistent rate of growth than nearly every other industry [28]. The medical device industry is increasingly significant in the contribution it makes to countries' economic productivity [29]. If the market is being fully exploited, the principal difference between any two production locations is likely to be labour costs. When product standardization and market saturation give rise to cost pressures and price competition in developed countries, those companies that want to increase their export business, transfer technology and investment abroad, which means the developed

countries shift production to the developing countries [30]. Foreign investment took place because of the product and factor market imperfections [5]. Researchers proposed the relationship between market imperfections and sustainable opportunities, by recognizing and combining known supply and demand elements of the market [31]. The developing countries technological capabilities are often improved and expanded, this results in a stable technical ability enhancement via continuous accumulation. Technological capability enhancement is strongly correlated with foreign investment growth and vice versa [26, 32].

Investment clearly implies strong consumption now, with the expectation of more consumption at a later time [33]. Despite the low rates of return on investment, China has attracted a great deal of foreign investment in many industries, while other selected countries were not attracting investment, or are even losing foreign capital [34]. China is an immense, constantly changing market with huge opportunities for expansion in the field of medical devices [35]. With adopted foreign capital, management know-how and trained labour, China possesses the capacity to absorb high technology industry, especially in the medical device industry [36]. China has been the fastest growing economy, expanding at 10.0 percent annually, driven by exports and investment. High priority is given to transform the economic structure from an export driven to a consumption driven economy during the period of the "National 12th Five-Year Plan"[3] [37].

[3] Five-Year Plan (FYP) is a series of social and economic development initiatives, which renews every five years. The Five-Year Plan was shaped by the Communist Party of China, who plays a leading role in mapping strategies for China's economic development, setting growth targets and launching reforms. First FYP: 1953-1957, the rest can be done in the same manner. So 11th FYP is from 2006-2010 and 12th FYP is from 2011-2015.

Chapter 3 Global Medical Device Market

3.1 Global healthcare expenditure

According to the World Health Organization (WHO) report, the total global healthcare expenditure reached US$ 7,593 billion in 2014 [38]. Figure 3-1 shows the global healthcare expenditure. In addition, Table 3-1 describes the total expenditure on health as a % of GDP by different income groups[4]. Obviously, the United States spent a lot of money on their healthcare, more than other countries. This expenditure is the sum of both public and private spending on health goods and services.

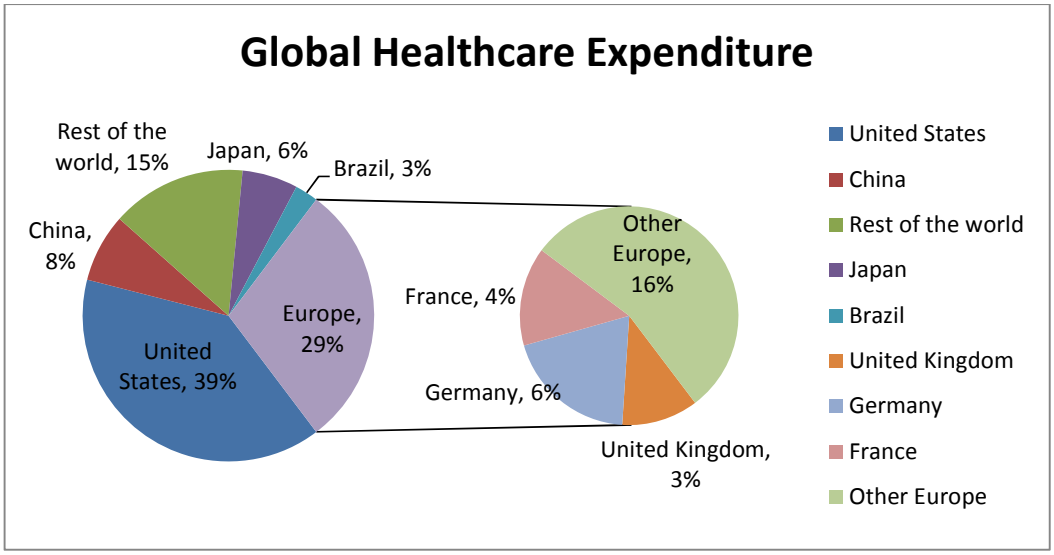

Figure 3-1 Global Healthcare Expenditure.

Source: WHO, 2015

Table 3-1 Total Expenditure on Health as % of GDP by Different Income Groups.

Year	Low Income	Lower-middle income	Upper-middle Income	High Income	Global
2000	4.6	4.4	5.9	10.0	8.3
2008	5.4	4.3	6.3	11.1	8.5

[4] The groups are: low income, US$975 or less; lower-middle income, US$976-3855; upper-middle income, US$3856-11,905; and high income, US$11,906 or more. Countries are divided among these income groups according to 2010 gross national income (GNI) per capita, calculated using the World Bank Atlas method (WHO).

Source: World Health Statistics 2011 [39]

Table 3-1 shows the expenditure on health as a % of GDP in high-income countries changed significantly between 2000 and 2008 from 10.0% to 11.1%. The reason why high-income countries changed much more than other income groups is that the trend of their total health expenditure as a % of GDP increased obviously from 2005 to 2010 according to Table 3-2 which is shown below.

Table 3-2 illustrates the total expenditure on health as % of GDP of some main high income countries such as United Kingdom, United States, Japan, China and Netherlands.

Table 3-2 Health Expenditure, Total (% of GDP) from the year 2005 to 2010.

	2005	2006	2007	2008	2009	2010	Income level
China	4.7	4.6	4.4	4.6	5.1	5.1	Upper middle income
Germany	10.7	10.6	10.5	10.7	11.7	11.6	High income
Japan	8.2	8.2	8.2	8.5	9.5	9.5	High income
Netherlands	9.8	9.7	9.7	9.9	12.0	11.9	High income
United Kingdom	8.3	8.5	8.4	8.9	9.8	9.6	High income
United States	14.7	15.9	16.1	16.5	17.6	17.9	High income

Source: The World Bank data, 2011 [40]

3.2 Global medical device market

According to the Espicom Business Intelligence report [41], the global medical device market value is estimated at US$ 250 billion in 2011, with a 5% growth over year 2010's US$ 235 billion. The United States is the world's largest medical device market, its sales accounted for around 42.4% of the global medical device market, which achieved nearly US$ 106 billion in 2011. Figure 3-2 describes the global medical device market size in 2011. Moreover, per capita expenditure of the US achieved US$ 339, which is the third

highest in the world, after Denmark and Switzerland. The main driving forces for the US market growth are: a huge demand for medical devices, high level of medical expenses, scale of 300 million population and an aging population. The US is home to some of the largest medical device manufacturers in the world. Table 3-3 shows the Top Ten medical device manufacturers in the world and seven of them are from the US, obviously, the US is the most significant medical device market in the world. The US, Japan, Germany, France and Italy account for 13.1% of global population and 76% of global medical device use, conversely, the five most populous countries such as China, India, Brazil, Indonesia and Pakistan account for about half of the global population but only 4.4% of medical device use in the world [42].

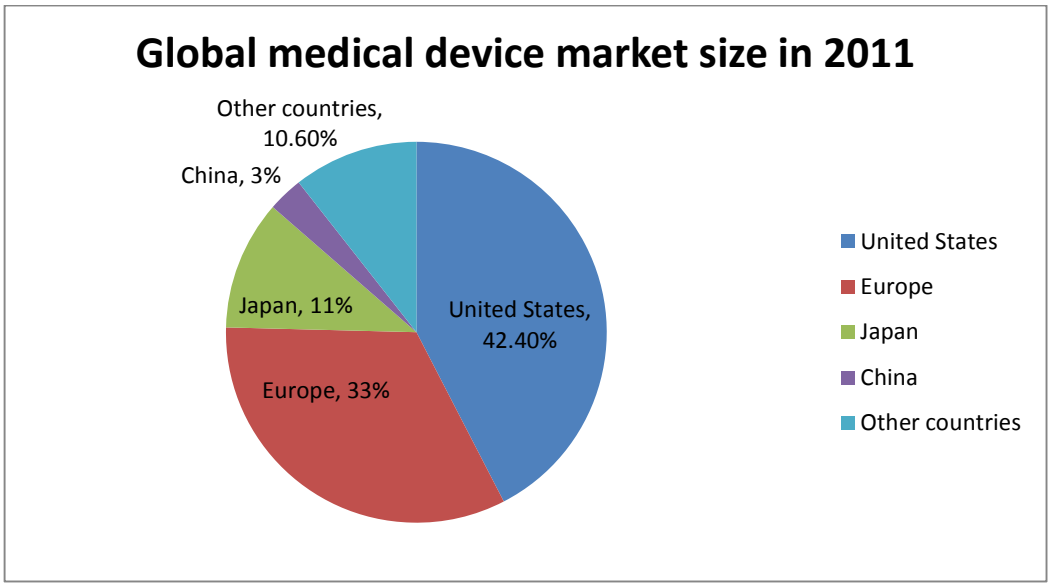

Figure 3-2 Global Medical Device Market Size in 2011.

Source: Espicom Business Intelligence, 2012 [41]

Table 3-3 Top Ten Medical Device Manufacturers in 2011.

Rank	Company	Revenue/Sales (Billion US Dollars)	Country
1	Johnson & Johnson	23.6	United States
2	Siemens Healthcare	17.4	Germany
3	GE Healthcare	16	United States
4	Medtronic	14.6	United States
5	Baxter International	12.6	United States

6	Philips Healthcare	11.2	Netherlands
7	Abbott Laboratories	8.4	United States
8	Boston Scientific	8.2	United States
9	Covidien	7.8	Bermuda
10	Becton Dickinson	7.2	United States

Source: MPO Medical Product Outsourcing [43]

As Figure 3-2 shows, China holds just 3% of the global medical device market size, China is still one of the fastest growing medical device markets in the world. According to the Frost & Sullivan forecast, the growth rate of global medical devices will increase 4% to 6% annually in the next few years and China's entire medical device market is expected to double, reaching US$ 53.7 billion by 2015 [37]. A detailed analysis of the Chinese medical device market will be shown in the following sections.

3.2.1 Global *in vivo* diagnostics market

With increasing emphasis on chronic disease prevention, the global diagnostic imaging device (*in vivo* diagnostics) market is expanding. The annual growth rate of the imaging device market share is 4.8% from year 2000 to 2008; global imaging device market share reached US$ 14.7 billion according to WHO [44].

Tomography, as one of the imaging technologies, has a huge market potential in some emerging economies such as China, India and Brazil. Moreover, the global market of ultrasound equipment continues to expand due to technology development. According to Global Data research [45] report forecasts, the market share of ultrasound equipment will increase by 7.3% annually and rise to US$ 5.2 billion by 2015 because of breast cancer and cervical cancer detection and cardiovascular imaging applications.

From the year 2001 to 2008, as the technology matures, the growth rate of the ultrasound market share increased 5.1% annually. The main reason for the growth is that high demand of medical institutions. Moreover, compared to other imaging devices, ultrasound equipment has its own advantages: lower cost, portable, lightweight and safe. So a lot of medical institutions have the ability to buy ultrasound equipment even some small health care centres.

From the year 2001 to 2008, the average annual growth rate of X-ray systems and computed tomography (CT) increased slowly because of the market size, which is also relatively mature and stable. CT will be at a low level in technological innovation compared with other types of diagnostic imaging equipment. So the investments in CT will not increase dramatically in the future.

From the year 2001 to 2008, breast screening and diagnosis equipment has a lower speed of growth compared to ultrasound. X-ray systems have a global market share of (4.1%) according to Global Data research [45] report. However, with the increased incidence of breast cancer and the development of nuclear imaging technology, the global market share of breast screening and diagnosis equipment will reach 6.9% per year [45]. Therefore, the market prospects of breast screening and diagnosis equipment is very optimistic.

From the year 2001 to 2008, the growth rate of the global market share of magnetic resonance imaging (MRI) was higher than 6.6% annually because of the rapid development of the MRI area and diseases diagnosis applications. For example, 3Tesla (3T) MRI, the new MRI, brings with it important tools to help physicians improve the accuracy of diagnoses and treatments of broad categories of diseases including stroke, heart disease, musculoskeletal, epilepsy and brain tumours [46]. However, the use cost of MRI is relatively expensive. Under the circumstances of a global financial crisis, Global Data research [45] report forecasts the global market share growth rate of MRI will be slightly decreased (6.1%). Table 3-4 shows the global diagnostic imaging device market trends from 2000 to 2008.

Table 3-4 Global Diagnostic Imaging Device Market Trends from 2000 to 2008.

Category	Market share (2008) (Million US Dollars)	Average annual growth rate % (2000-2008)
X-ray systems	3743.77	3.8%
Ultrasound	3326.97	5.2%
MRI	2563.66	6.6%
Nuclear imaging equipment	2294.83	4.6%

CT	2060.45	3.6%
Breast X-ray equipment	728.24	4.1%
Total	14717.92	4.7%

Source: Medical Economic News, 2010 [47]

3.2.2 Global medical imaging for cancer and breast cancer detection/treatment

According to WHO's report [48], cancers of the breast, lung and colon are among the top ten causes of death of older women globally. The incidence (new cases) of breast cancer is much higher in high-income countries compared to low-and middle-income countries, but mortality is similar. This is due to the availability of better treatment in the high-income countries. Worldwide, breast cancer accounts for 22.9% of all cancers in women. In 2008, breast cancer caused 458,503 deaths worldwide and 13.7% of cancer deaths in women according to World Cancer Report, [49]. Figure 3-3 shows the estimated annual number of new cases and deaths for breast cancer in different income groups in 2008 (World Bank method, mentioned before).

In recent years, clinical treatment found that, an average 10-year survival rate of breast cancer achieved 60%. The survival rate of breast cancer after early treatment achieved 80%. And after earliest treatment, the survival rate closer to 100%. Therefore, early detection and treatment for breast cancer is quite significant.

In the diagnostic imaging equipment, all of the imaging devices can diagnose breast cancer to some degree, but they are often inaccurate. Specialized diagnostic imaging of breast cancer is still scarce in the medical device market because the breast imaging workflow is still immature. So the breast cancer diagnostic equipment market has great commercial potential. In recent years, the market for cancer diagnostic equipment is expanding because the number of cancer deaths is increasing worldwide and the incidence of cancer tends to occur at a lower age. The developed countries are scrambling to develop cancer-related diagnostic scanning equipment in order to get a good position in this huge potential market. Table 3-5 illustrates the market size for the breast cancer detection medical devices from 2004 to 2007. According to the Frost & Sullivan forecast, by 2014, the market size for X-ray mammography, breast ultrasound, MRI and nuclear breast

imaging will be 925.2, 532.3, 12.7 and 27.5 million US dollars respectively. The market has the great potential.

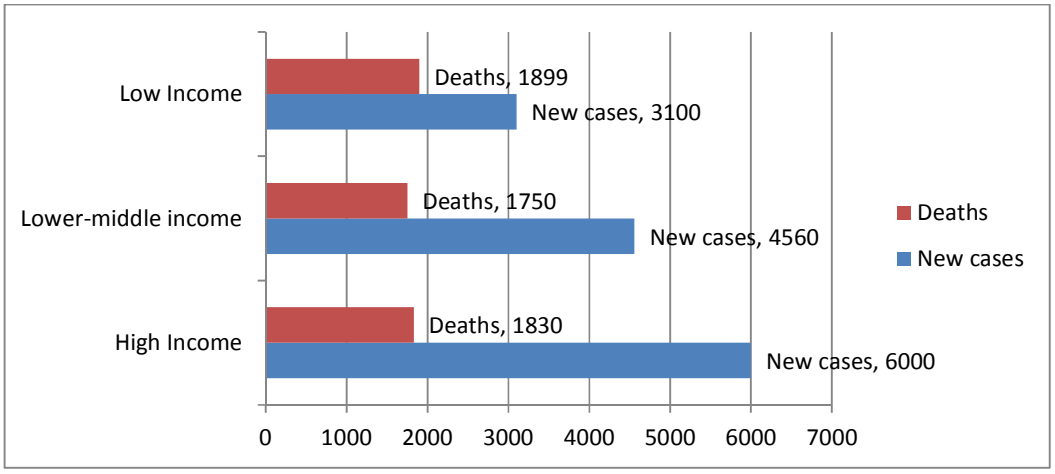

Figure 3-3 Estimated Annual Number of Deaths for Breast Cancer in Different Income Groups in 2008.

Source: Global status report, [50]

Table 3-5 The Market Size of the Breast Cancer Detection Medical Devices from 2004 to 2007. (Million US Dollars)

Year	X-ray Mammography	Breast Ultrasound	MRI Breast Coil	Nuclear Breast Imaging	Total Market
2004	256.0	150.5	11.3	5.6	423.4
2005	245.8	184.8	12.2	7.0	449.8
2006	406.7	218.9	12.9	7.0	645.5
2007	630.0	258.6	13.1	8.6	910.3

Source: Frost & Sullivan, [51]

3.3 Introduction of main medical device companies

GE Healthcare, Siemens Healthcare and Philips Healthcare are the leaders of the global *in vivo* diagnostics market. In the year 2009, they accounted for 69% of global market share in diagnostic imaging equipment. GE Healthcare accounted for 26.1% of global market share in diagnostic imaging equipment, ranking it first. Followed by Siemens Healthcare and Philips Healthcare, they accounted for 21.7% and 21.2% of market share,

respectively. Therefore, to study and analyse the main large medical device companies' market performance is helpful to understand the global *in vivo* diagnostics market.

3.3.1 GE Healthcare

The history of General Electric Company (GE) can be traced back to the late 1870s. By 1890, famous scientist, inventor, Thomas Edison, established the Edison General Electric Company. By aligning multiple businesses to bring innovation to the marketplace, Edison laid the path for today's GE [52]. In 1892, Edison General Electric Company and the Thomson-Houston Company combined. They are called the General Electric Company. GE is the only one company who has more than 60,000 patents and two Nobel Prize-winners in the world. GE is a well-known globally diversified multinational company which has a set of technical, manufacturing and service industries as a whole, and is committed to be a global leader in each industry to obtain their business.

GE Healthcare is an affiliated enterprise of GE. GE healthcare is headquartered in London. The revenue achieved US$ 16 billion in 2011 and ranked in the third place among the medical device manufacturers in the world according to Table 3-3. Moreover, GE healthcare is the leader of global *in vivo* diagnostics market. The predecessor of GE Healthcare is the Victor Electric Company, acquired by GE in 1926. The Victor Electric Company operated an X-ray business and were making X-ray machines in 1896 (one year after Roentgen's discovery) [53]. Victor Electric depends on its innovative products became the main supplier in the X-ray machine area. Based on these advantages, GE healthcare developed a series of CT scanning, ultrasound, MRI as the representative *in vivo* diagnostics equipment, and gradually became the industry leader.

3.3.2 Siemens Healthcare

The company "Telegraphen-Bauanstalt von Siemens & Halske" founded by Siemens. Werner von Siemens laid the foundations in 1847 for today's Siemens AG in Germany. His invention is based on the telegraph. [54]. Headquartered in Berlin and Munich, Siemens is now one of the world's largest electrical engineering and electronics companies.

Siemens Healthcare (Med) formerly was known as Siemens Medical Solutions, and, Siemens Medical Systems. Med is one of the Germany's Siemens' business groups, and it is also one of the famous medical device manufacturers and suppliers in the world. Med focused on the research and development of CT and MRI systems. Med has the new medical technology; quality service and complete solution that can help their customers achieve tangible, sustainable clinical results and economic benefits.

According to Table 3-3, the sales of Med reached US$ 17.4 billion in 2011, it is higher than its main competitors such as GE Healthcare (US$ 16 billion) and Philips Healthcare (US$ 11.2 billion), ranked in the second place among the global top ten medical device manufacturers.

3.3.3 Philips Healthcare

Royal Dutch Philips Electronics was founded by Gerard Philips in 1891 in Eindhoven in Netherlands. The company begun manufacturing carbon-filament lamps and had become one of the largest producers in Europe. Philips' introduced its first innovation in X-ray and radio technology during the industrial revolution in Europe [55]. Philips ranked first in the global lighting market, top three in the medical patient monitoring systems and is

in the Top Ten in the diagnostic imaging systems in the world. Moreover, Philips has more than 80,000 patents.

Philips Healthcare provides one of the world's most outstanding medical system products to the customers and their ultrasound equipment and X-ray equipment are world leaders. As Table 3-3 shows, the total sales of Philips Healthcare reached US$ 11.2 billion in 2011. Figure 3-4 illustrates Philips ultrasound equipment revenue and service revenue from 2006 to 2010. The market value from 2008 to 2010 is estimated by Philips.

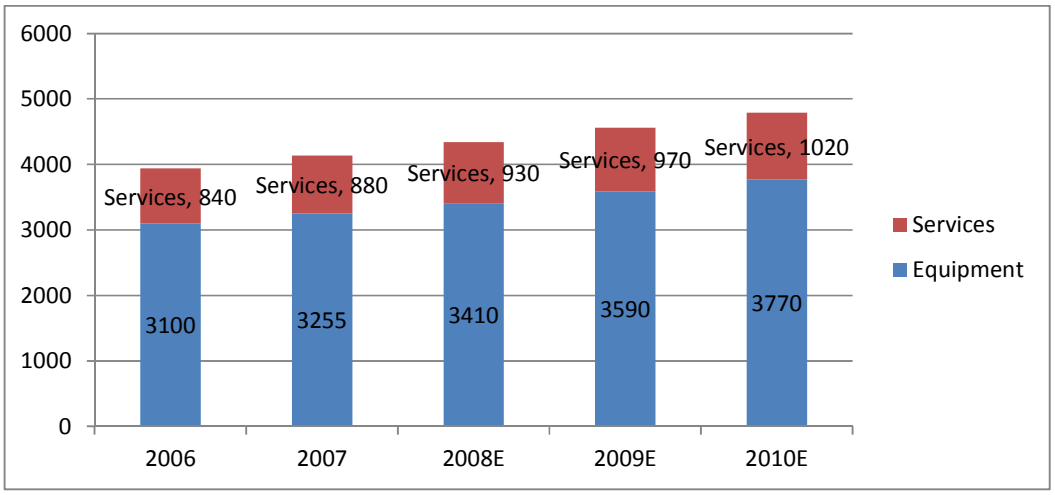

Figure 3-4 Philips Ultrasound Market Value (Million Euros).

Source: Philips Internal Report, [56]

3.4 Market share of *in vivo* diagnostics device manufacturer by market segment

GE, Siemens and Philips are the largest players in the *in vivo* diagnostics market. Besides them there are some other companies such as Toshiba, Hitachi, Aloka, etc. who have specialized exclusively on medical diagnostic imaging devices. The medical imaging market positions of the largest players are close. There is of course a difference in medical imaging market position. GE leads in the CT and MRI market, Philips leads in the X-ray (Mammography) and ultrasound market. Moreover, Siemens leads in global Customer Relationship Management (CRM) and Healthcare Information Technology (IT)/Health Services according to the Siemens Healthcare report [57]. The following will show how the largest players engage with the medical device market, together they represent nearly

70% of the global medical imaging device market, their performance in the different market segments, for example CT, ultrasound etc. is valuable to understand.

3.4.1 CT market share

Figure 3-5 shows the market share for CT of the three main large medical imaging manufacturers. Obviously, the three imaging leaders have a strong position in the CT market, GE, Siemens and Philips account for 35%, 20.1% and 14.7% respectively. They account for about 70% of the CT global market.

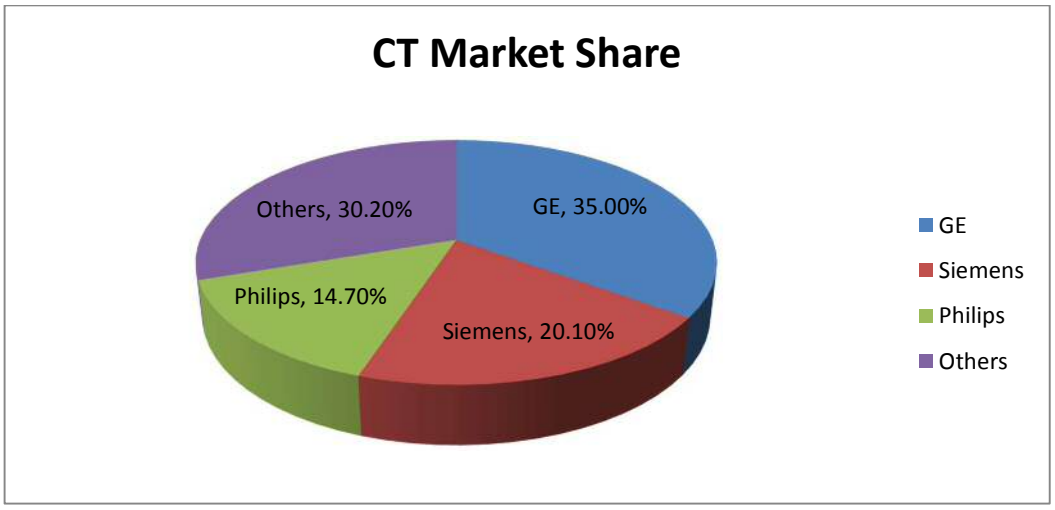

Figure 3-5 Market Share of CT in 2008.

Source: Frost & Sullivan, [58]

3.4.2 Ultrasound market share

Figure 3-6 describes the market share of ultrasound by the main large medical imaging manufacturers. Obviously, GE, Siemens and Philips account for 64% of the global total ultrasound market share. Moreover, GE gained one point share to 26% global (25%, in 2005). Other companies such as Aloka, Hitachi and Medison etc. account for 22% of the market share and Toshiba accounted for 14% of the ultrasound market share in 2006 (same as 2005). Both GE and Philips appear to be coming on strong in ultrasound. The market share of Siemens and Toshiba are close, at 16% and 14% respectively.

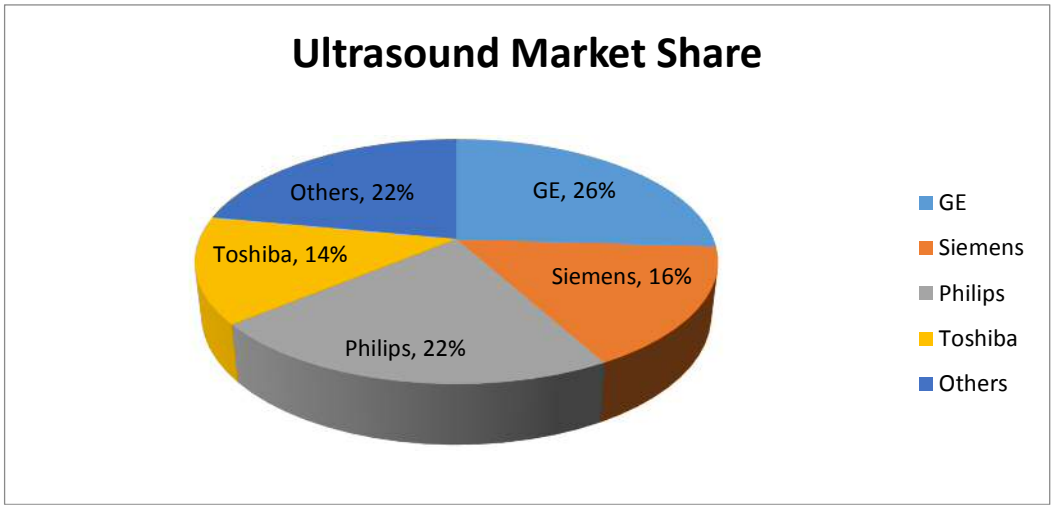

Figure 3-6 Market Share of Ultrasound in 2006.

Source: Philips Internal Report, [59]

3.4.3 MRI market share

Figure 3-7 shows the market share of MRI by the main three large medical imaging manufacturers in 2008. For MRI market, three medical imaging device market leaders- GE, Siemens and Philips represent 70% of the market share. The latter two together comprise 35% of the market share, the same as GE's market share.

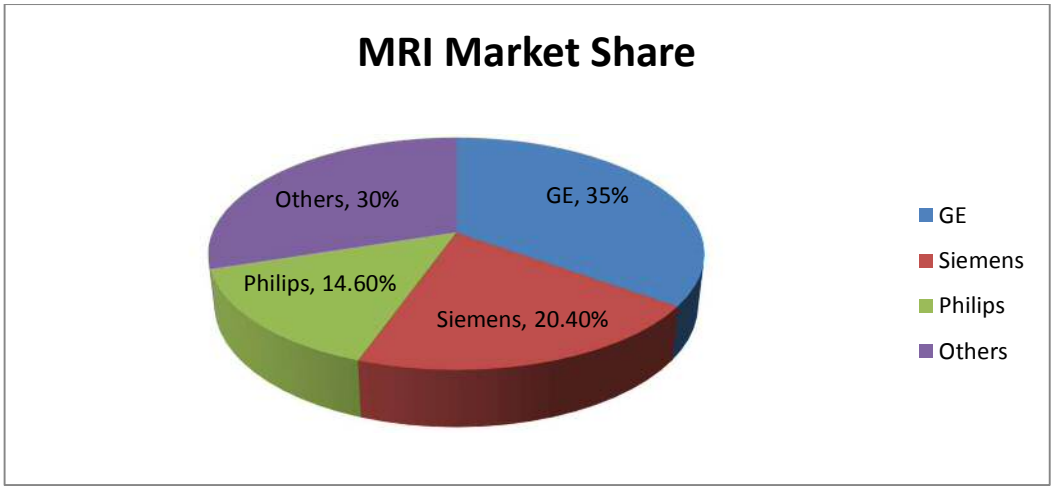

Figure 3-7 Market Share of MRI in 2008.

Source: Frost & Sullivan, [58]

3.4.4 X-ray (Mammography) market share

Breast cancer is the most common type of cancer in women. Every woman has a 1/8 life time chance of developing it. Mammography is the most valuable method for detecting potentially cancerous anomalies in the breast [60]. Mammography can reduce breast cancer mortality by 20% to 30% in women over 50 years old in high-income countries [49]. Figure 3-8 shows the market share of X-ray (Mammography) taken by the main three large medical imaging manufacturers in 2008. Philips is the leader in the X-ray market. Philips is the X-ray market leader accounting for 24% of market share.

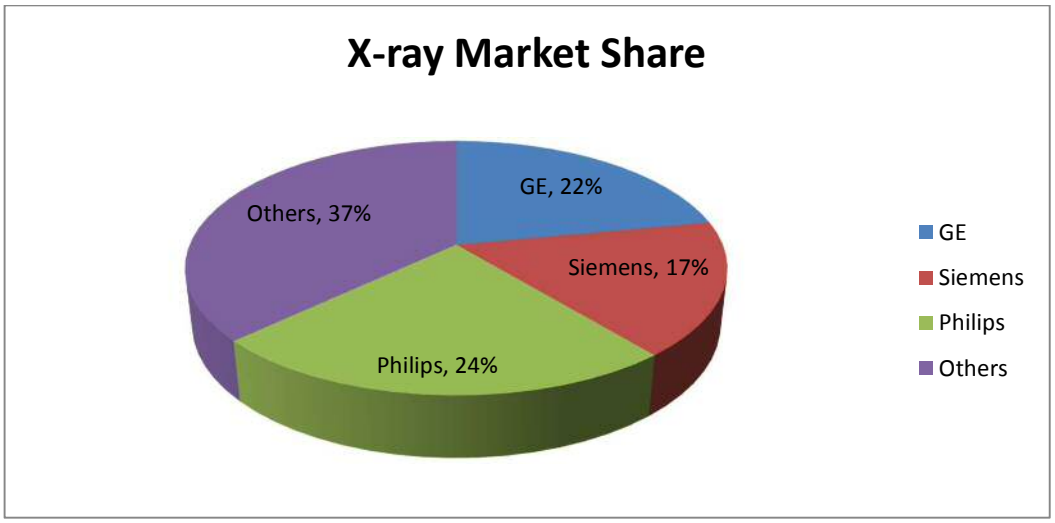

Figure 3-8 Market Share of X-ray in 2005.

Source: Philips Internal Report, [61]

Chapter 4 The Chinese Medical Device Market

4.1 China's healthcare industry

With the rapid growth of its economy, China has expanded its healthcare expenditure. According to Figure 3-1 and Table 3-2, China accounts for only 4% of global healthcare expenditure and its healthcare expenditure, as a percentage of GDP[5], accounted for just 5.1% of the economy in 2009. During the years from 2001 to 2011, China's total annual healthcare expenditure gradually increased. Figure 4-1 shows total healthcare expenditure as a percentage of GDP from 2001 to 2011.

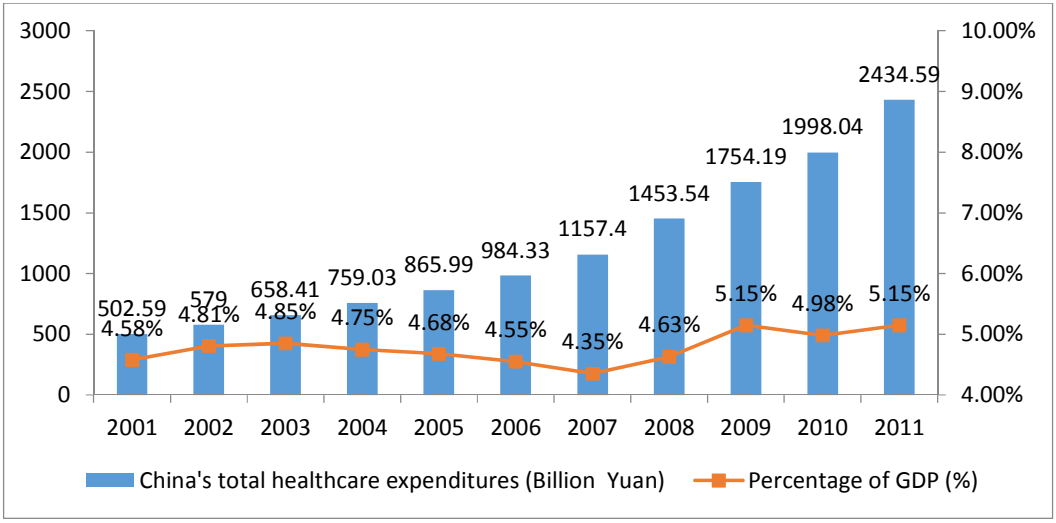

Figure 4-1 China's total healthcare expenditures and percentage of GDP (2001-2011).

By comparison, in 2009, total healthcare expenditure, as a percentage of GDP for the: US accounts for 17.7%; Germany-11.7%; UK-9.7%; Japan-9.5%, even Brazil is 8.8%, which is higher than China [62]. The above data suggest that China has the capacity to substantially improve its healthcare service. A significant factor is that China has the largest population in the world (1,331 million in 2009), which is nearly 4 times that of the US (307 million) and about 21 times that of the UK (62 million) in 2009 [63]. More specifically, in 2009, total health expenditure per capita[6] for the US was US$ 7,990 and UK was US$ 3,445 while China was only US$ 191 [64]. The medical fee-for-service

[5] Gross domestic product (GDP) is the market value of all officially recognized final goods and services produced within a country in a given period of time.
[6] Total health expenditure per capita is the sum of public and private health expenditures as a ratio of total population.

system in China leads to many Chinese people needing to pay for the services from their own pocket. The medical fee-for-service system creates barriers to seeking adequate quantity and quality of care for poor families and individuals [65]. The Chinese government is trying to make medical services for people affordable, especially for the low-income people. The government has determined to carry out healthcare reform, and invested 850 billion yuan (about US$ 140 billion) in healthcare systems covering infrastructures and equipment from 2009 to 2011 [66]. Figure 4-2 shows the detailed allocation of the investment funds. According to the government report, the reform has five aspects: (1) establish a basic medical security system and medical insurance system; (2) establish a national drug system; (3) improve the basic medical and health service system; (4) improve the equality of basic public health services; and (5) promote the reform of public hospitals. All this will inevitably lead to spending on capital goods, most notably medical devices [67]. Despite these reforms, the Chinese government still needs to be vigilant both technically and politically due to the challenges of: affordability and accessibility to medical devices [68].

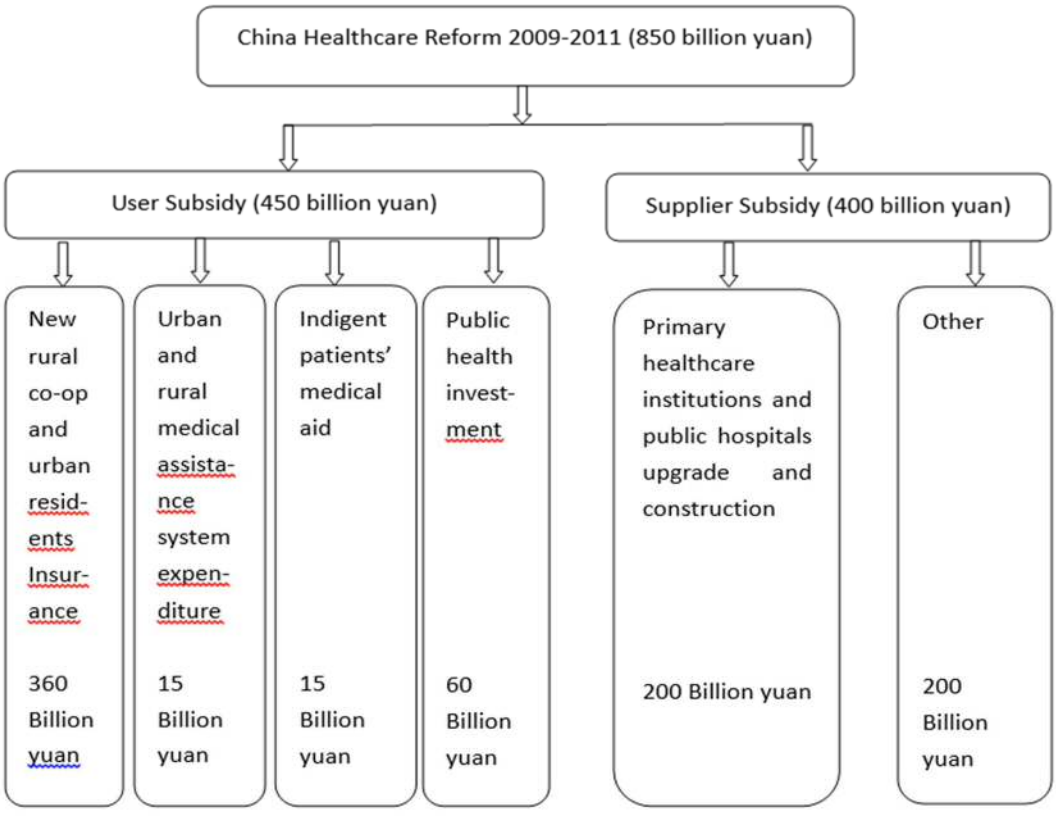

Figure 4-2 Breakdown of China's healthcare reform.
Source: Author's compilation

4.2 China's medical device market

"Medical Device" — covers a very broad area, from simple but essential products (such as a wheelchair) to complex high-tech products (such as a pacemaker), which involves many areas such as mechanical, electronic… Therefore, medical devices have many different types of products. Medical dressings and disposable products such as cotton wool, gauze, bandage and some surgical instruments do not have high-tech skill requirements, so the product differentiation is small, many manufacturers can produce these products, and the competition is very fierce. However, as the high-end medical imaging devices, CT, Ultrasound, MRI and X-ray are produced by few companies, the Chinese high-end medical device market is dominated by these companies.

4.2.1 Background

The global medical device market is highly centralized [69]. The market share of the developed countries accounted for more than 80% of the global medical device market share (US: 42.4%, Europe: 33%, Japan: 11%) in 2011 [41]. With superior know-how in technology and/or management, international companies are typically larger than domestic companies and have a competitive advantage due to the economies of scale [5]. According to Charles Hill and Vernon's product life cycle theory, the developed countries will export their production and technology from their relatively saturated market to the developing countries due to the market pressures and other competition in their established markets [7, 30, 70]. Despite China only accounting for 3% of the global medical device market share [41], this study shows that the developing countries' medical device markets are experiencing rapid growth, especially in China. Increasing medical expenditure, rising healthcare consumption and health awareness improvements are all possible factors in promoting the development of the Chinese medical device market. The Chinese government's healthcare reform has injected additional "power" into the development of the medical device market. In fact, by the end of 2011, the Chinese medical device industry output value was 688.42 billion yuan, total percentage of GDP is 1.40%. Figure 4-3 shows the Chinese medical device industry output value and its total percentage of GDP, its value continues to climb from 2001 to 2011. In 2011, the percentage of medical device industry output value accounted for 1.40% of Chinese GDP.

Although the output value of the medical device industry is currently a limited proportion of the national economy, Figure 4-3 shows a rising trend year by year except 2008.

The Chinese high-end medical device market is dominated by the US, Germany and Japan, it is dependent upon imports from these countries. The US is the most significant medical device market in the world. Close to 60% of all medical devices consumed around the world are produced by American companies [28]. According to the APCO Worldwide market analysis report, 90% of value-added high-tech medical devices are foreign made, which accounts for 70% of the Chinese medical device market [69]. These high-tech medical devices include CT, MRI, Ultrasound, X-ray, implants and assistive devices.

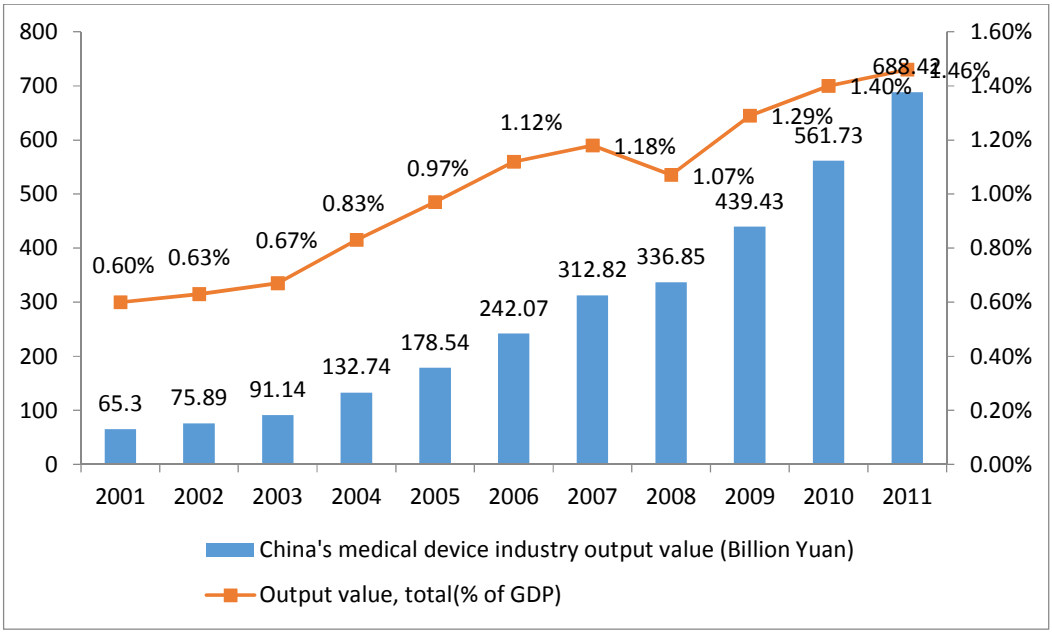

Figure 4-3 China's medical device industrial output value and its total (% of GDP).
Source: National Bureau of Statistics of China [3, 71]

China's high-end medical device market is dependent upon imports and dominated by foreign companies' products, especially for the diagnosis and treatment devices. Table 4-1 shows the Chinese medical market trade statistics according to the China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE) in 2010. The overall trend of the Chinese healthcare market shows that export value is higher than import value; hence the export value of the pharmaceutical and medical device industry is higher than the import value. However, only the import

value of medical diagnosis and treatment devices is higher than the export value, which took a 29.05% share of total import volume in China. By comparison, medical dressings, disposable products, health protection and recovery products, dental equipment and materials, total only 6.8% of import volume, which is only one-quarter of the import volume of the medical diagnosis and treatment sector.

Table 4-1 China's import and export structure of medicines and health products, 2010.

(Unit: million US Dollars)

Trade name		Export Value	Export value growth rate annually (%)	Share in total export volume (%)	Import Value	Import value growth rate annually (%)	Share in total import volume (%)
Total		39,733.10	24.87	100	20,464.36	23.98	100
1.Traditional Chinese Medicine		1,944.47	22.78	4.89	687.95	22.61	3.36
2.Pharmaceuticals		23,930.02	28.17	60.23	12,440.84	20.53	60.79
3.Medical Devices		13,858.61	19.83	34.88	7,335.57	30.45	35.85
3.1	Medical dressings	4,687.51	11.95	11.8	207.77	25.63	1.02
3.2	Disposable products	1,922.27	15.42	4.84	880.76	27.73	4.3
3.3	Medical diagnosis and treatment	4,543.60	25.56	11.44	5,944.73	30.34	29.05
3.4	Health protection and recovery products	2,416.41	30.87	6.08	149.37	83.83	0.73
3.5	Dental equipment and materials	288.82	16.51	0.73	152.94	21.37	0.75

Source: CCCMHPIE, 2011 [72]

More specifically, Table 4-2 illustrates the trade statistics for medical devices in China in 2010. The total export value of medical devices reached US$ 13.86 billion in 2010, while

the total import value reached US$ 7.3 billion. North America and Asia are the main export target areas for China, which accounted for 29.23% and 33.7% of the total export volume; the US and Japan are the main export target countries, which absorbed 27.91% and 10.39% of the total export volume respectively. Europe and North America are the main exporters to China, which accounted for 39.01% and 31.41% of the total import volume. Germany and the US are the main importing countries, which provide 17.34% and 30.71% of the total import volume.

Table 4-2 China's import and export markets of medical devices in 2010.

(Unit: million US Dollars)

Country		Export Value	Export value growth rate annually (%)	Share in total export volume (%)	Import Value	Import value growth rate annually (%)	Share in total import volume (%)
Total (All countries)		13,858.61	19.83	100	7,335.57	30.45	100
Asia		4,669.96	12.87	33.7	1,938.77	29.28	26.43
Europe		3,631.06	18.53	26.2	2,861.38	34.38	39.01
North America		4,051.03	24.48	29.23	2,303.79	25.81	31.41
1.	U.S.	3,867.61	24.72	27.91	2,252.64	26.48	30.71
2.	Germany	778.06	14.72	5.61	1,271.74	35.43	17.34
3.	Japan	1,440.07	-13.5	10.39	1,113.90	26.99	15.18

Source: CCCMHPIE, 2011 [73]

For the Chinese medical device market, with growth from many sources of demand (unmet clinical needs, aging population, disease profiles, etc.), medical diagnosis and treatment devices still have a great growth potential. China now has a fee-for-service healthcare system financed largely by payments from patients, employers and health insurance companies [74]. However, many patients especially high income people are willing to pay more money by themselves for the highest quality of care, especially for the treatment of cancers, heart disease, cerebrovascular disease, etc., which needs to use high-tech medical diagnosis and treatment devices or high-grade drugs, which is not

affordable for low income people. For example, the average fees for CT whole body scan is nearly 2500 yuan (about US$ 400) in China, this is not a small expenditure for low income people; they always choose the most economic ways to treat their diseases. However, China's health institutions especially the Tier-3 hospitals[7] have a strong demand for high-end diagnostic devices due to the rising number of visits and inpatients, changed disease profiles, etc.. Figure 4-4 illustrates the main information of the Chinese medical device market [75].

Increased aging population and healthcare spending are the main driving forces of the medical device industry rapid development. Notably, China relies heavily on foreign imports for medical devices, especially for the medical imaging devices, which have high technical barriers. Hospitals are the largest distribution channel for medical devices. Tier-3 hospitals imported nearly 100% of their medical devices such as CT, MRI, etc. Moreover, 90% of local manufacturers focus on low value-added low-cost medical products. The discrepancy between foreign and Chinese medical device companies is commonly attributed to the high entry barriers for the high-end medical imaging market: producing more technologically advanced devices is capital-intensive, require lots of technical knowledge and generally has a long time to market. Faced with a lack of financing, 90% of Chinese companies are unable to invest in R&D for high-end devices and it is more difficult for the Chinese companies to reproduce these devices. Foreign companies provide the training and maintenance of these devices to increase market reliance and to ensure lasting profitability [35].

[7] There are three levels of Chinese hospitals: Tier-3 Hospitals (6%) tend to be the best and highest level (first class) hospitals, which may offer the most comprehensive medical treatment; complex clinical diagnosis, advanced scientific research and R&D abilities, which are provincial and municipal hospitals in big cities; Tier-2 Hospitals (34%) are providing comprehensive medical services, basic teaching and research functions, which are municipal hospitals in smaller cities as well as district and county hospitals; Tier-1 Hospitals (25%) are grass-roots healthcare institutions, providing basic medical services, which are the primary healthcare facilities in small towns; Other healthcare institutions account for 35% of total medical institutions.

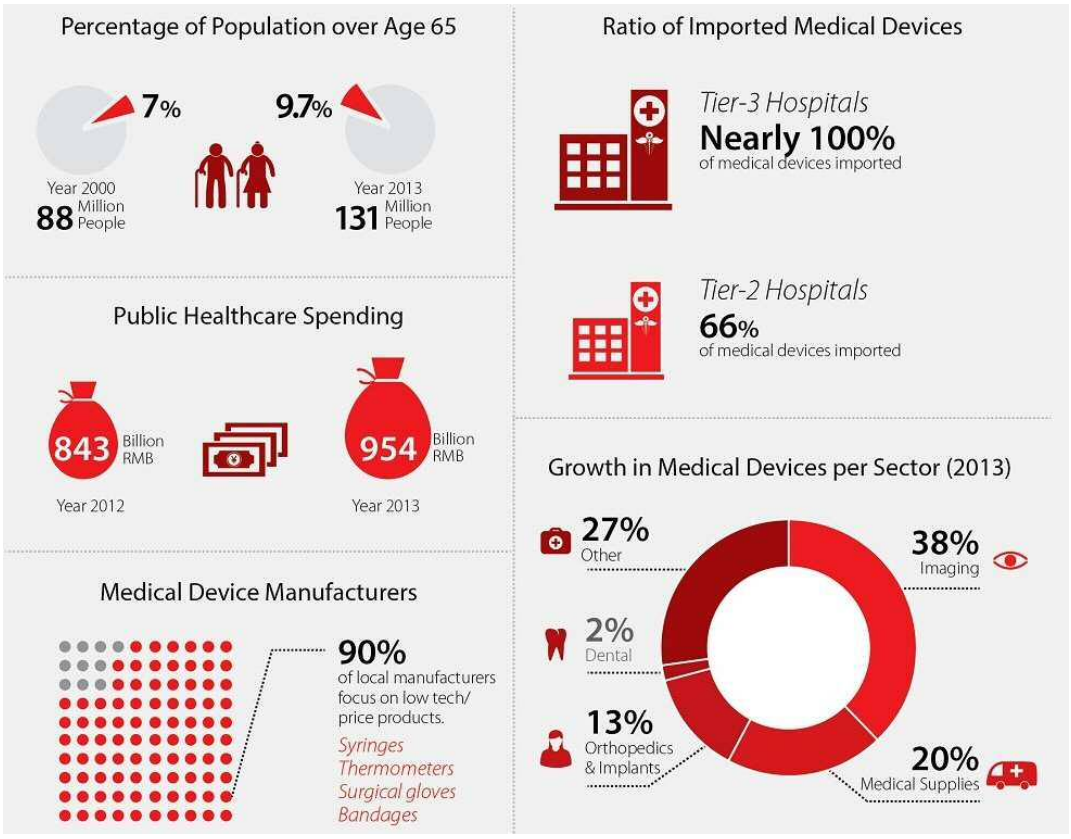

Figure 4-4 China's medical device industry at a glance.

4.2.2 Data

The improvement of medical and health services has greatly increased the market capacity for the Chinese medical device industry. The important medical device industry drivers are (1) *demographics*, the percentage of the global and Chinese population above 65 years old is growing. (2) *unmet clinical needs*, the trend of using new medical devices or products to address diseases or medical needs that previously were simply not treated is increasing. (3) *procedure penetration*, there is a tendency among doctors to use more medical products and procedures. (4) *pricing*, positive pricing trends have generally been favourable in the medical device industry. Medical products are not selected on the basis of price. (5) *geographic reach*, the market potential for the highly-populous less-developed countries (including China) is very compelling [76].

The data sources are mainly collected from government reports. Data for medical device industry revenues from 2000 to 2012 was collected from the China Statistics Yearbook

on High Technology Industry [77]. Data on the number of hospital visits and number of hospitals were extracted from the China Health Statistical Yearbook [78]. Data on 65+ population was collected from the China Statistical Yearbook [79], and is presented in Table 4-3. Other data are collected from United Nations (UN) and their organizations and specialized agencies such as the International Monetary Fund (IMF) and World Bank; some non-commercial agents such as the China Association for the Medical Devices Industry (CAMDI), China Association of Medical Equipment (CAME) and Chinese Hospital Association (CHA).

Table 4-3 Chinese healthcare related data.

Year	Medical device industry revenues (million yuan)	Number of hospital visits (million)	65+ population (million)	Number of hospitals (Unit)
2000	55,813	1,286	88	16,318
2001	62,797	1,250	91	16,197
2002	73,404	1,243	94	17,844
2003	88,048	1,213	97	17,764
2004	130,300	1,305	99	18,393
2005	175,218	1,387	101	18,703
2006	236,382	1,471	104	19,246
2007	302,975	1,638	106	19,852
2008	325,563	1,782	110	19,712
2009	425,937	1,922	113	20,291
2010	553,090	2,040	119	20,918
2011	673,860	2,259	123	21,979
2012	777,200	2,542	127	23,170

The China Statistical Yearbook datasets contain data from every mainland Chinese province and city except: Hong Kong, Macao and Taiwan. It also includes the most important Chinese statistical data, which is an annual digest of economic and social development. The major data sources are obtained from annual statistical reports and sample surveys. This study does not include lower level health institutions in the number of hospitals, such as grass-roots health care institutions[8], specialized public health

[8] Grass-roots Health Care institution include community health centre and station, sub-district health centre, village clinic, outpatient department, and, clinic (infirmary).

institutions[9] and other Institutions. This is because, in China, high-end medical diagnosis devices are always located in Tier-3 hospitals as other health institutions do not have the resources to purchase these expensive medical devices.

4.2.3 Methods and empirical analysis

This study analyses the Chinese medical device market using quantitative research methodologies (regression analysis). Many data sets are collected from official statistics, which are created by government departments or other organizations. Although there is some limitation to official statistics, many researchers still use this method to analyse markets because it saves cost and time, gives access to high-quality data and provides the opportunity for longitudinal and cross-culture analysis, etc. [80]. Some forms of official statistics are very precise, such as births and deaths data [80] and population census data [81]. Data analysis makes the developing trends more clearly understandable. Trend analysis can be used to predict the future value of the market. More and more researchers have started to focus on the past and its importance for understanding the present situation and for predicting the future more effectively via in-depth historical analysis. In the population section, this study uses Neural Network Time Series prediction, to predict the total Chinese population and the number of 65 year olds and above from 2011 to 2020. Neural Networks are widely used in many areas but few researchers have used it for population prediction. Therefore, analyses of the data trends from the past to the present shows the importance and changing trends for medical devices demand.

In the real economic environment, one variable is affected by several factors. Multiple regression analysis has been selected as the research method in this study. Assume the regression equation is:

$$Y_i = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_i x_i + \mu_i \qquad (4-1)$$

where Y is the dependent variable, x are the explanatory variables, μ the stochastic disturbance term, and i the ith observation [82]. Using the data in Table 4-3, we set:

[9] Specialized Public Health Institution include Chinese Centre for Disease Control and Prevention (CDC), specialized disease prevention and treatment institution, health education centre, maternal and child health centre, emergency centre, centre for blood collection & supply, centre for health supervision and centre for family planning service.

Y =medical device revenues, x_1 =number of hospital visits, x_2 =65+ population, x_3=hospital number. From Microsoft Excel we obtained the following regression result:

$$\widehat{Y_i} = -1026663.83 + 370.46x_1 + 6119.01x_2 + 3.70x_3$$
$$t = (-7.6946) \quad (6.1616) \quad (1.5722) \quad (0.2008) \qquad (4-2)$$
$$R^2 = 0.9928 \quad \bar{R}^2 = 0.9904$$

where $\widehat{Y_i}$=estimator of Y_i, $\bar{R}^2$=adjusted R, t= t value, used for t test.

Regression (see Table 4-4) shows that the number of hospital visits, 65+ population and hospital number together explain 99% of the variation in medical device revenues. The estimated value of the coefficients of the: number of hospital visits, 65+population and hospital number are 370.46; 6119.01 and 3.70, respectively.

Table 4-4 Multiple regression analysis results.

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.996392262
R Square	0.99279754
Adjusted R Square	0.99039672
Standard Error	23813.59461
Observations	13

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	3	7.03513E+11	2.34504E+11	413.524344	5.89061E-10
Residual	9	5103785595	567087288.3		
Total	12	7.08617E+11			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*
Intercept	-1026663.83	133427.07	-7.69	3.02E-05	-1328496.831	-724830.822
number of hospital visit	370.46	60.12	6.16	1.66E-04	234.448567	506.46896
65+ population	6119.01	3891.99	1.57	0.15	-2685.27294	14923.298
hospital number	3.70	18.44	0.20	0.85	-38.00456748	45.40976

Hypothesis testing (the t test) assumes H_0: β_i=0, (i=1, 2, 3). Regression results (Table 4-4) illustrates that the t of $\widehat{\beta_1}$= 6.1616, t of $\widehat{\beta_2}$= 1.5722, t of $\widehat{\beta_3}$= 0.2008. The t test of significance decision rules is shown in Table 4-5.

Table 4-5 The t test of significance: decision rules.

Type of Hypothesis	H_0: The Null Hypothesis	H_1 : The Alternative Hypothesis	Decision Rule: Reject H_0 if
Two-tail	$\beta_1=\beta_1^*$	$\beta_1\neq\beta_1^*$	$\lvert t\rvert>t_{\alpha/2}$,df
Right-tail	$\beta_1\leq\beta_1^*$	$\beta_1>\beta_1^*$	$t>t_{\alpha}$,df
Left-tail	$\beta_1\geq\beta_1^*$	$\beta_1<\beta_1^*$	$t<-t_{\alpha}$,df

Notes [82]: β_1^* is the hypothesized numerical value of β_1.

$\lvert t\rvert$ means the absolute value of t.

t_α or $t_{\alpha/2}$ means the critical t value at the α or $\alpha/2$ level of significance.

df: degrees of freedom, $(n-2)$ for the two-variable model, $(n-3)$ for the three-variable model, and so on

The same procedure holds to test hypothesis about β_1.

If we assume α[10]=0.05, degrees of freedom (df) = n-4= 13-4 =9[11]. According to percentage points of the t distribution (Appendix 1), $t_{\alpha/2,df}$=$t_{0.05/2}$(9)=2.262. Therefore, t_1=6.1616>$t_{0.05/2}$(9), which is significant, so reject H_0, which means that the number of hospital visits has significant impact on medical device revenues. t_2=1.5722<2.262 and t_3=0.2008<2.262, so accept H_0: β_2=0 and H_0: β_3=0, which are insignificant.

The regression model is based on several assumptions, one of the assumptions is that "There is no exact collinearity between the x (explanatory) variables". Insignificant t values but a high overall R^2 is one of the signals for multicollinearity [82]. After correlation using Excel we obtained r_{12} =0.9644, r_{13}= 0.9423, r_{23}= 0.9831, which means three explanatory variables are highly correlated. Thus, we regress Y on x individually.

[10] α (0< α<1) is known as the level of significance.
[11] n means number of observations

Table 4-6 Y and x_1 regression analysis results.

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.992251249
R Square	0.984562541
Adjusted R Square	0.983159136
Standard Error	31535.32702
Observations	13

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	6.97678E+11	6.97678E+11	701.552517	2.57875E-11
Residual	11	10939245351	994476850.1		
Total	12	7.08617E+11			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*
Intercept	-609743.6033	35388.49349	-17.2299961	2.6283E-09	-687633.1522	-531854.0543
number of hospital visit	553.3439799	20.89128221	26.48683668	2.5788E-11	507.3625777	599.325382

Therefore, the relationship between Y and x_1 could be:

$$\widehat{Y_i} = -609743.60 + 553.34x_1$$
$$t = (-17.23) \qquad (26.49) \qquad R^2 = 0.98 \qquad (4-3)$$

The regression (equation 4-3) shows that the number of hospital visits variable is highly significant, and $t_{\alpha/2,df}$=$t_{0.05/2}$(11)=2.201. t_1=26.49>$t_{0.05/2}$ (11), therefore reject H_0. The same with equation (4-2)'s results, which means the number of hospital visits has significant impact on medical device revenues.

Table 4-7 Y and x_2 regression analysis results.

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.980909914
R Square	0.96218426
Adjusted R Square	0.958746466
Standard Error	49356.65704
Observations	13

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	6.8182E+11	6.8182E+11	279.884167	3.59461E-09
Residual	11	26796875539	2436079594		
Total	12	7.08617E+11			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*
Intercept	-1748028.048	123092.6949	-14.2009081	2.0251E-08	-2018953.243	-1477102.854
65+ population	19391.36416	1159.095439	16.72973899	3.5946E-09	16840.2123	21942.51602

Table 4-7 shows the relationship between Y and x_2 is:

$$\widehat{Y_i} = -1748028.05 + 19391.36x_2$$
$$t = (-14.20) \quad (16.73) \quad R^2 = 0.96 \qquad (4-4)$$

The regression (equation 4-4) and t test (t_2=16.73>$t_{0.05/2}$ (11)=2.201) illustrates that the 65+ population variable was statistically insignificant, whereas now it is highly significant.

Table 4-8 Y and x_3 regression analysis results.

SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.96151241
R Square	0.924506115
Adjusted R Square	0.917643034
Standard Error	69737.33142

Observations	13

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	6.55121E+11	6.55121E+11	134.707165	1.63777E-07
Residual	11	53496249335	4863295394		
Total	12	7.08617E+11			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*
Intercept	-1897611.305	190203.0518	-9.97676581	7.5668E-07	-2316245.399	-1478977.211
hospital quantity	114.0216304	9.824080196	11.60634157	1.6378E-07	92.39897565	135.6442851

Table 4-8 shows the relationship between Y and x_3 is:

$$\widehat{Y}_i = -1897611.31 + 114.02x_3$$
$$t = (-9.98) \quad (11.61) \quad R^2 = 0.92 \quad (4-5)$$

t_3=11.61>$t_{0.05/2}$ (11)=2.201, and regression equation (4-5) shows that the number of hospitals now has a significant impact on medical device revenues, whereas in equation (4-2) it had no effect on medical device revenues.

Therefore, compared with other variables, hospital quantity is one of the drivers in the Chinese medical device market, but the number of hospital visits and 65+ population played a more important role than hospital quantity.

4.3 Analysis

4.3.1 Number of hospital visits

According to the previous analysis, the correlation equation (4-3):

$$\widehat{Y}_i = -609743.60 + 553.34x_1$$

which means there is a positive linear correlation between the number of hospital visits and medical device industry revenues, which means every one million change in the number of hospital visits will cause a positive change of 553.34 million yuan in medical

devices revenues. This result shows that the number of hospital visits is a vital contributor to the Chinese medical device market.

Table 4-9 Number of visits and inpatients in health institutions.

Year	Visits (Million)			Inpatients (Million)		
	Hospital	Township Health Centre	Total (Include other institutions)	Hospital	Township Health Centre	Total (Include other institutions)
2008	1,782	827	4,901	73.92	33.13	114.83
2009	1,922	877	5,488	84.88	38.08	132.56
2010	2,040	874	5,838	95.24	36.30	141.74
2011	2,259	866	6,271	107.55	34.49	152.98

Source: China Health Statistical Yearbook, 2012

According to Table 4-9, the general trend in the number of visits and inpatients in health institutions increased from 2008 to 2011. In 2011, the total number of visits in health institutions achieved 6,271 million. The hospitals have 2,259 million visits, which accounts for about 36% of total visits. Grass-roots health care institutions have 3,806 million visits, which accounts for about 60.7% of the total visits. The number of medical and health institutions, and visits and inpatients in health institutions has experienced growth every year, consequently there is an increased demand for medical devices, especially the good quality, multi-functional medical systems. The frequency of use of medical devices will accelerate and the renewal period will be shortened.

4.3.2 Demographic factors

The huge population and aging population are one of the factors for the growth of China's pharmaceutical market [83], as well as the medical device market. According to equation (4-4):

$$\widehat{Y}_i = -1748028.05 + 19391.36x_2$$

the regression shows that every one million change in 65+ population will cause a positive change of 19391.36 million yuan in medical devices revenues. It is clear that the 65+ population is the most important driver of the medical device market.

The UN identifies, populations who have reached the age of 60 years as "older population" [84]. Moreover, the UN considers a country to be aging when 10% of their total population is aged over 60 or 7% of their total population is aged over 65 [85]. According to the National Bureau of Statistics of China's Sixth National Population Census[12] in 2010 [86], the total population of China reached about 1.37 billion, where people aged 60 and above accounted for about 0.18 billion (13.26% of the total population), people aged 65 and above accounted for about 0.12 billion (8.87% of the total population). According to the IMF and UN statistics, China has 0.11 billion people that are over 65, which is 8.19% of the total population (1.34billion). Which means that China has entered the "aging society" category.

Figure 4-5 shows the changing trend of the Chinese population between 1980 to 2010 [87]. In addition, it is necessary to understand China's profile in respect of the "aging society". There is no direct data on the percentage of 65 years olds and above from 1980 to 2010, but we can extrapolate how many 65 years olds and above there are from the UN Population Division [88]. After calculation, we can evaluate that the approximate percentage of 65 year olds and above in China from 1980 to 2010, see Figure 4-6. All data shown in Appendix 2.

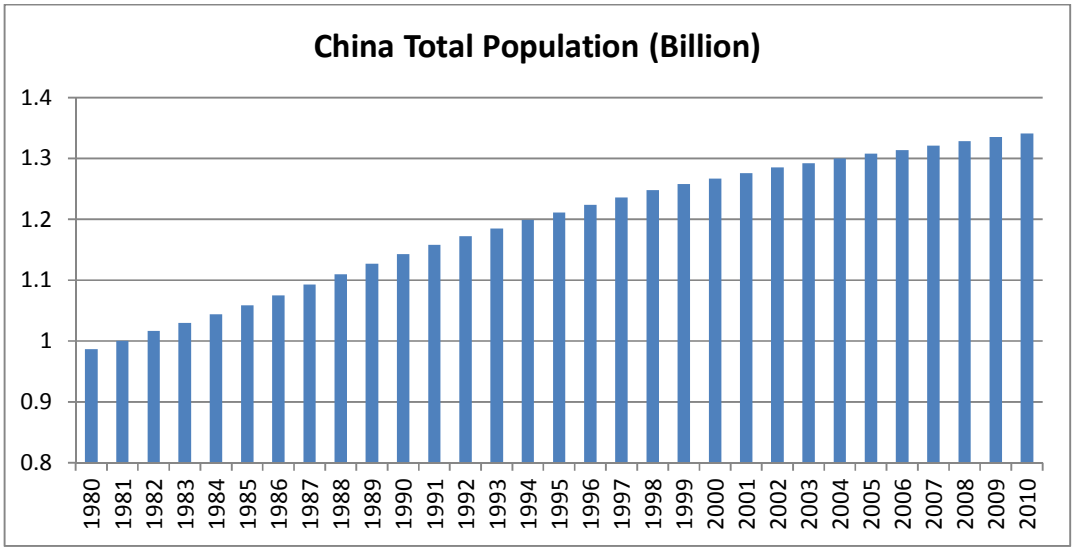

Figure 4-5 Chinese population from 1980 to 2010.

Source: IMF, 2012 [87]

[12] Peoples Republic of China have six national population census before. The first one was in the year of 1953, second one was in 1964, third one was in 1982, then 1990, 2000 and 2010.

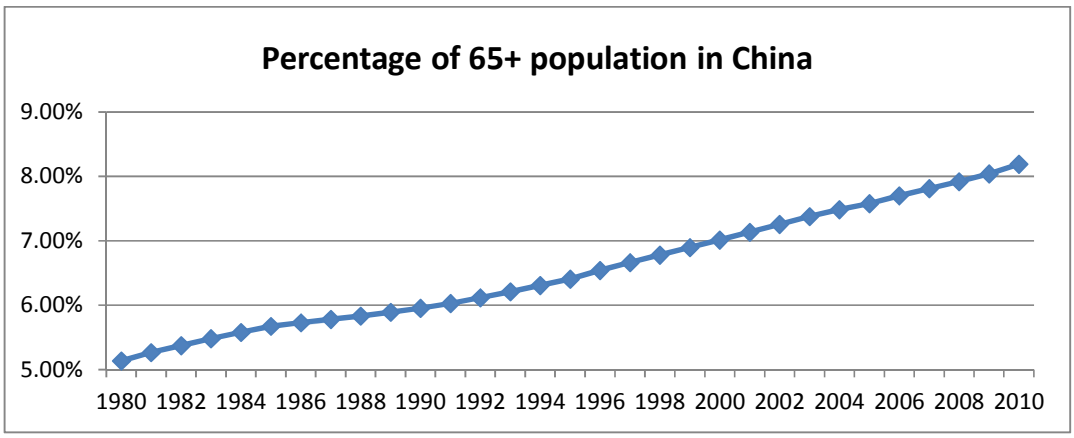

Figure 4-6 Percentage of 65 year old and above population in China from 1980 to 2010.

Source: UN, 2011 [88]

From the year of 1990 to 2010, the Chinese population increased from 1.14 billion to 1.341 billion. However, the population growth rate declined since 1990 [89]. Figure 4-7 shows the trend of Chinese total population growth rate from 1980 to 2010; data taken from Appendix 2. The total population increased slowly, but the population growth rate decreased year by year since 1990 due to the decrease in fertility and mortality [90]. The reduction in population growth rate speeds up the growth in the aging population. An important need of the "aging society" is high quality healthcare, because the elderly are experiencing increasing rates of chronic diseases [91]. Therefore, the Chinese medical device market is set to expand.

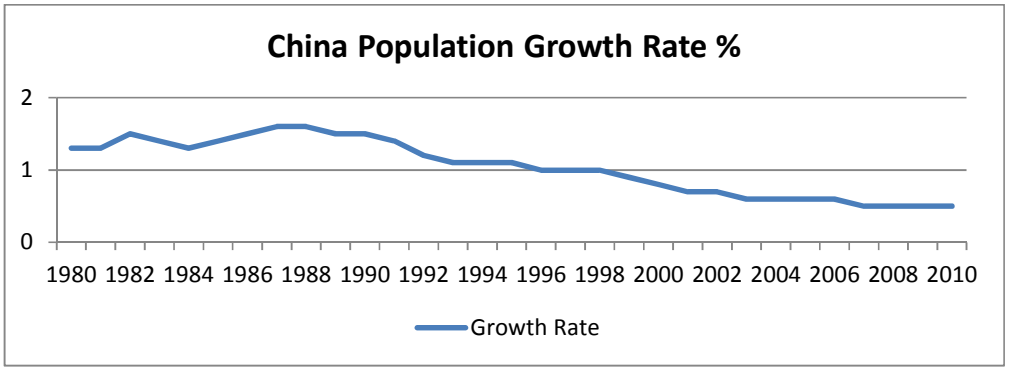

Figure 4-7 China population growth rate from 1980 to 2010.

Source: The World Bank, 2012 [89]

Prediction is used in a number of areas. Recently there has been a growing interest in applying neural networks to dynamic systems identification, prediction and control [92]. Back Propagation (BP) Neural Networks are widely used with great success. McClelland, Rumelhart and Hinton [93] established the Parallel Distributed Processing (PDP) models. The PDP research group proposed the BP algorithm, this method solved the problem of a lack of suitable training methods for the multilayer perceptron (MLP), and this greatly assisted the development of neural networks.

Neural networks are increasingly used by business and management for prediction and systems optimization. This includes financial analysis and forecasting [94], bankruptcy prediction [95] and stock market prediction [96]. Luo and Huang [97], Xie and Li [98] have discussed the prediction of population based on neural networks.

We use neural network time series prediction in this research. This is a simple way to predict population. In the neural network time series prediction, the method of nonlinear autoregression (NAR) [99] has been chosen because there is only one series involved (here it is Population). The future value schema of a time series *y(t)* is shown in Figure 4-8.

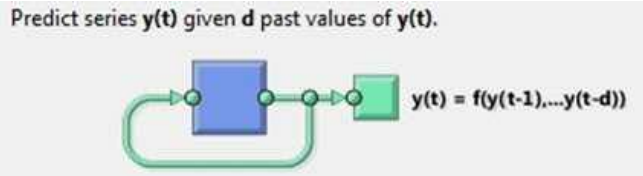

Figure 4-8 Diagram of NAR neural network.

Using a neural network time series prediction based on the real population from 1980 to 2010, the predicted total population in China from 2011 to 2020 is extrapolated in Figure 4-9.

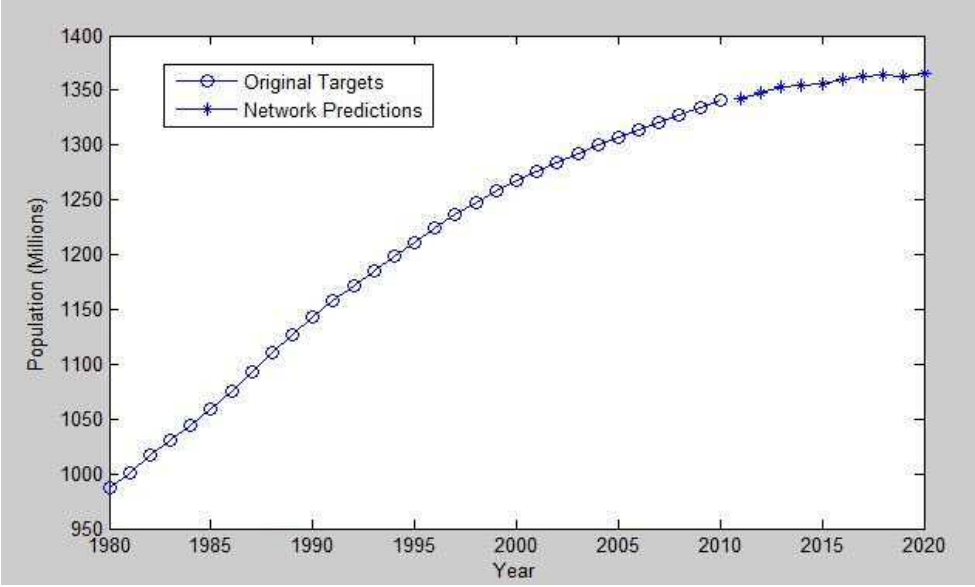

Figure 4-9 Real Chinese population and predicted population.

After training many times, it was found that the optimum number of delays is 5, and the number of hidden neurons is 16 (see Figure 4-10), this minimized the error of the neural network[13] to 0.029528, which gives the best prediction performance. Detailed data shown in Appendix 4.

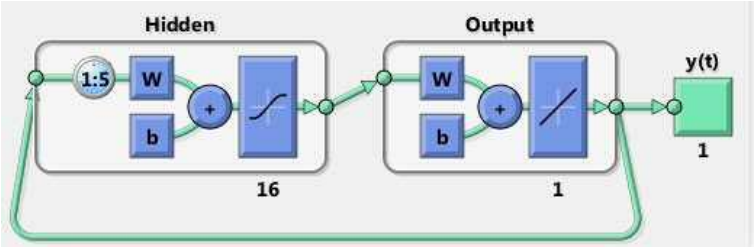

Figure 4-10 Diagram of NAR neural network used for Chinese total population prediction.

The World Bank data show that the Chinese total population in 2011 and 2012 is 1,344.13 million and 1,350.70 million respectively, while the results of the neural network time series prediction shows the population is 1,342.32 million (2011) and 1,347.63 million (2012) [100]. The error is relatively small and a reliable prediction has been achieved. Therefore, a Neural Network performs well in predicting the population. This method is

[13] Neural network error= $\sqrt{\sum_{i=1980}^{2010}(P_i - D_i)^2}$, where P_i is year i population, D_i is year i predicted population.

used to predict the 65 year old and above population in China, with results illustrated in Figure 4-11.

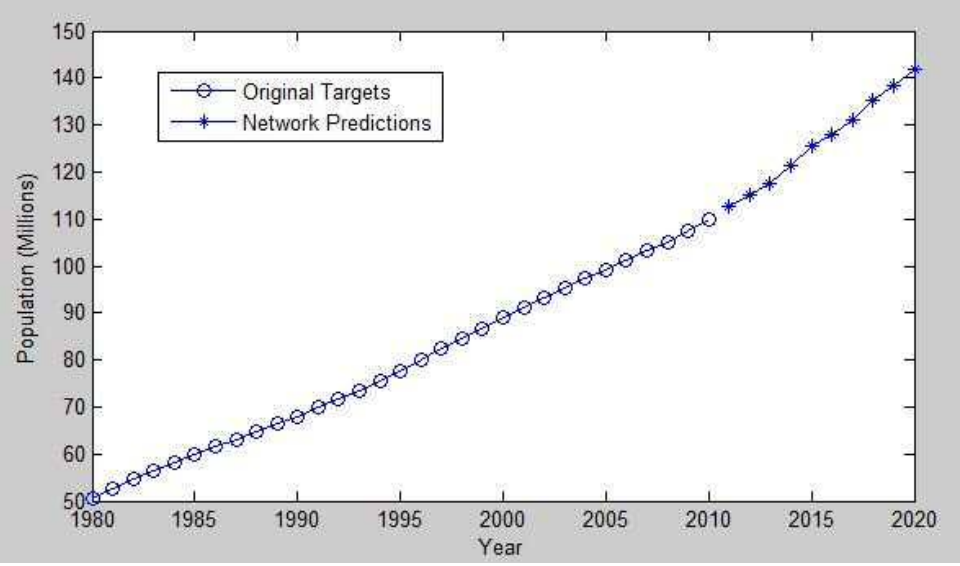

Figure 4-11 Real Chinese 65+ population (1980-2010) and predicted 65+ population (2010-2020).

Predicting the population for 65 year olds and above permits prediction of a major element of the future value of the medical device market based on past records. Figure 4-11 illustrates the real Chinese aged 65 and over population from 1980 to 2010 and the predicted 65 year olds and above population from 2011 to 2020. The predicted Chinese 65 year olds and above population from 2011 to 2020 is reported in Appendix 3.

4.3.3 The number of hospitals in China

Equation (4-5):

$$\hat{Y}_i = -1897611.31 + 114.02x_3$$

illustrates that the number of hospitals has a positive linear correlation with medical device revenues. According to the China Health Statistical Yearbook, by the end of 2011, the number of Chinese medical and health institutions reached 954,389 (see Table 4-10). Grass-roots health care institutions account for more than 90% of the total number of medical institutions. With the recent reform of China's healthcare system, this situation is changing. According to the healthcare system reform program, the Chinese government

invested 850 billion yuan to promote the development of medical and healthcare service from 2009. Due to the technology level of the medical devices in these health care institutions was lower than in hospitals, the speed of upgrading medical devices will cause substantial growth in the coming years. This indicates that there is huge potential for the Chinese medical device market.

Table 4-10 Number of medical and health institutions.

Institutions	2008	2009	2010	2011
Hospital	19,712	20,291	20,918	21,979
Grass-roots Health Care Institution	858,015	882,153	901,709	918,003
Specialized Public Health Institution	11,485	11,665	11,835	11,926
Other Institution	2,268	2,462	2,465	2,481
Total	891,480	916,571	936,927	954,389

Source: China Health Statistical Yearbook, 2012 [101]

In summary, China now has hundreds of thousands of medical and healthcare institutions; increasing numbers of hospital visits; unmet medical needs has made these medical and health institutions require more and more medical devices. China has a large population, who have experienced rapid economic development, which has resulted in continuous improvement of people's living standards; the descending population growth rate, means that the aging population has become a vital element in driving the medical device market. The Chinese medical device industry is in a period of development and expansion, there are very broad market opportunities. The huge demand provides a good market opportunity for medical device companies. The improvement of Chinese medical and health services provides a good development platform and market capacity for the Chinese medical device industry.

Other driving forces such as ownership rate of medical devices among the main hospitals and diseases cannot easily use quantitative methods to assess their impact.

4.3.4 The ownership rate of medical devices among the main hospitals

The China Health Statistical Yearbook summarized the number of medical devices in the main hospitals and the percentage of medical devices. Although no official data was collected after 2004, we can get some data from other agents such as CAME and CHA in order to explore the medical device market investment situation in China. Table 4-11 and Table 4-12 illustrate the number and percentage of medical devices in the main hospitals.

Table 4-11 Number of medical devices in the main hospitals in China (units).

Device / Year	1996	1998	2000	2001	2004
Electrocardiograph	35,295	41,230	46,122	48,073	---
B-mode ultrasound	19,077	21,842	23,911	24,893	19,653
Colour Doppler Ultrasound	2,455	4,596	5,110	5,926	7,613
CT	2,549	3,543	4,247	4,760	4,752
MRI	356	512	604	714	1,110
Cardiac Monitor	19,108	27,580	39,995	47,024	---

Source: China Health Statistics, [102, 103]

Table 4-12 Percentage of medical devices in the main hospitals in China (%).

Device / Possession rate	1996	1998	2000	2001	2004
Electrocardiograph	88.1	90.2	92.8	93.7	---
B-mode ultrasound	87.1	89.3	91.8	92.7	83.0
Colour Doppler Ultrasound	15.4	22.0	29.0	32.8	35.7
CT	17.8	22.6	27.7	30.6	29.2
MRI	2.5	3.2	4.0	4.8	7.2
Cardiac Monitor	39.3	43.4	48.2	49.8	---

Source: China Health Statistics [102, 103]

Nearly 90% of the main hospitals purchased Electrocardiograph and B-mode ultrasound, because electrocardiograph and B-mode ultrasound are relatively cheap and are used widely, ordinary people can afford the diagnostic fees. In addition, many of electrocardiograph and B-mode ultrasound devices are indigenous products, there is

massive competition especially price competition in this area, which has reduced the profit margins, investment in these devices will not gain more profits. Table 4-11 illustrates that the units for Cardiac Monitoring were 47,024 in 2001, almost the same as Electrocardiograph, but its percentage in the main hospitals accounts for 49.8%, this is a large difference between Electrocardiograph's 93.7% in 2001. It means that with the high growth rate of the number of Cardiac Monitors, the market for these devices still has room for expansion. From both Table 4-11 and Table 4-12 we can understand that the market for Colour Doppler ultrasound, CT and MRI has great investment potential, especially MRI. This situation is caused for many reasons including the disease profiles, which are described below.

Today the Chinese hospital's reputation is said to rely on them possessing the latest and most expensive medical devices such as Colour Doppler ultrasound, CT and MRI [104], because most hospitals' revenues are generated by these expensive medical devices. In 1996, China had 2,549 CT scanners, 2,455 Colour Doppler ultrasound and 356 MRIs. The increasing speed of adoption of these medical devices is impressive. Until 2004, China had 4,752 CT scanners, 7,613 Colour Doppler ultrasound and 1,110 MRIs (see Table 4-11). According to CHA's report [105], China had 9,109 CT scanners in 2008, 10,101 CT scanners in 2009 and 11,242 CT scanners in 2010. With the increasing number of CT's, China had 5.5 CT scanners per million people in 2006, which increased to 8.6 CT scanners per million people in 2010, which shows a rapid growth. However, compared with other countries, the ownership rate of CT devices is relatively low. For example, Japan had 98 CT scanners per million people in 2006. Therefore, it can be predicted that there will be huge future demand for this kind of medical device in China.

4.3.5 The main diseases

With the increase in the population of elderly people; the improvement of people's living standards; population movements and the accelerated process of urbanization, disease profiles have altered significantly in China.

China now belongs to the upper middle income countries [106]; of the top ten leading causes of death in the middle income countries, seven are chronic disease-related deaths, which accounted for 91% of total deaths [107]. The higher burden of chronic diseases in

low- and middle income countries is manifest in China [108], which means these diseases will cost a great deal. Although digestive diseases, respiratory diseases, infectious and parasitic diseases are the top ten leading cause of death in low- and middle income countries, we need to focus more attention on cancers, cardiovascular diseases and cerebrovascular diseases, which account for the top three percent of total deaths in China [107].

Figure 4-12 and Figure 4-13 show the percentage of total deaths from the top five main diseases in Chinese cities and counties from 2003 to 2011. All the data are collected from the Ministry of Health of the People's Republic of China health statistics. Detailed data are shown in Appendix 5 (city) and Appendix 6 (county). Due to the scarcity of data; the years of 2007 and 2010 are not included.

Figure 4-12 illustrates the percentage of total deaths from the top five main diseases in Chinese cities from 2003 to 2011. By comparison, the top three leading causes of death in middle-income countries are cardiovascular diseases, cerebrovascular diseases and respiratory diseases [108-110], there were 2.8 million deaths from cardiovascular diseases in China in 2003 [109]. China has a different profile when compared with other middle-income countries. Cancers caused the highest mortality in China and has maintained the first position among the five leading causes of death in both the cities and counties, except in 2005, according to Figure 4-13. The major risk factors causing cancers are tobacco consumption, chronic infections, diet and lack of physical activity, etc. [111].

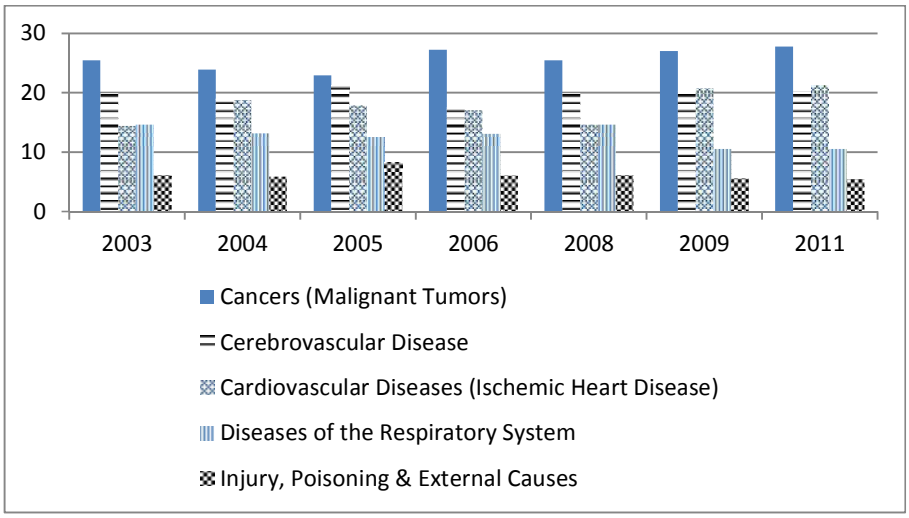

Figure 4-12 Percentage of total deaths from the top five main diseases in Cities.

Source: China Health Statistics [101, 112-118]

Compared with Figure 4-12 and Figure 4-13, cancers, cardiovascular diseases and cerebrovascular diseases are the top three causes of death in cities in China, but we cannot neglect respiratory diseases, which accounted for 23.45% of deaths in the counties in 2005 (see Appendix 6). Major risk factors for respiratory diseases include air pollution, tobacco consumption, occupational long term exposures, etc. [119]. Cerebrovascular diseases have reached second place among the ten leading causes of death in the developing countries, as well as in China. Major risk factors for cerebrovascular diseases are tobacco consumption, obesity and life stress, etc. Injury, poisoning and external causes are ranked in position five of the leading causes of death in both the cities and counties in China. From analysis of these diseases, it can be seen that tobacco is the greatest cause of health problems. Several diseases and conditions were added to the lists as being causally related to smoking [120].

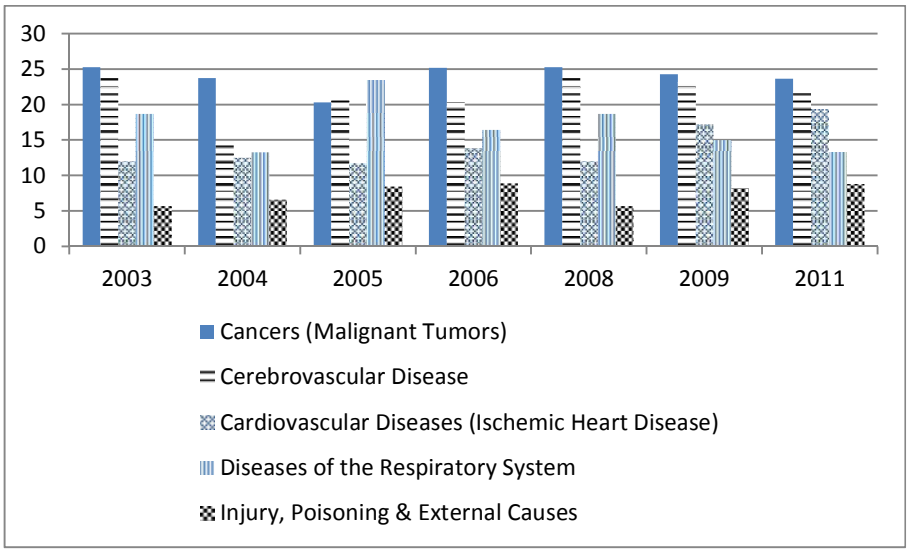

Figure 4-13 Percentage of total deaths from the top five main diseases in the County regions.

Source: China Health Statistics [101, 112-118]

Cancer is a leading cause of death globally, accounting for 7.6 million deaths in 2008 [121]. Nearly 70% of cancer deaths occurred in low- and middle-income countries. It is predicted that deaths from cancer will increase, with an estimated 13.1 million deaths in 2030 [122]. Cancer is a big problem for the society worldwide as well as for China.

According to the Chinese Cancer Registry Annual Report [123], the incidence of the top 10 most common cancers accounted for 76.39% of all cancers in China in 2012. Lung was the leading common cancer incidence with the rate of 18.74%, followed by stomach (12.67%), colon (10.30%), liver (10.04%), esophagus (7.74%) and breast (7.42%). In males, top incidence of common cancers are lung (22.14%), stomach (15.60%), liver (13.21%), colon (10.18), esophagus (9.57%) and prostate (3.12%), while in females, breast cancer was the leading common cancer with 16.81% of the incidence rate, followed by lung (14.36%), stomach (8.89%), liver (5.97%) and esophagus (5.39%). The mortality of the top 10 leading causes of cancer death accounted for 84.27% of all cancer deaths. Lung cancer was the leading cause of cancer deaths (25.24%), followed by liver (14.42%), stomach (14.33), esophagus (9.29%) and colon (7.88). In males, top mortality of cancers are lung (27.21%), liver (16.93%), stomach (15.45%), esophagus (10.39%) and colon (7.02%), while in females, top mortality of cancers are lung (21.91%), stomach (12.45%), liver (10.19%), colon (9.34%) and breast (7.54%).

Medical devices can guide optimized medical intervention plans, treat people's illnesses and reduce the discomfort caused by the disease. High quality, well designed medical devices provide safe and effective clinical care for patients [124]. With the gradual increase in the number of patients and mortality, the demand for diagnosis and treatment devices will inevitably increase. Good market prospects indicate that medical devices for these diseases have great investment potential.

4.4 Discussion

The correlation coefficient informs us about the direction and the relationship strength between the dependent variable and independent variables. This study suggests that the Chinese medical device market is not only driven by the three variables (number of hospital visits, 65+ population and number of hospitals) but is also impacted by the ownership rate of medical devices among the main hospitals; the main diseases and the government healthcare policy, which is not easily quantified. Regression analysis illustrates that people aged 65 and above play an important role in China's medical device market. The Chinese 65+ population are projected to be 236 and 334 million by the years 2030 and 2050, respectively [125]. Therefore, due to the importance of the aging population in China, we used neural network time series prediction to estimate the total

population and 65+ population from 2010 to 2020. Prediction results show that there is a smooth rising trend of Chinese 65+ population from 2010 to 2020, revealing that aging population plays an important role in the Chinese healthcare industry, which indicates that the Chinese medical device market has possible investment opportunities in the future.

The purpose of medical devices is to assist with: patient stratification, diagnosis, prognosis, treatment and treatment planning; the macroeconomic variables such as population structure; disease profiles and economic level can affect the demand for medical device services. Disease profiles affect the development of medicine as well as medical device capabilities and the total medical device market. Therefore, diseases should be one of the elements driving medical device investment.

The top five diseases have a significant impact on China's economy via healthcare costs and lost productivity. Popkin et al [126] estimated that diet-related chronic diseases (cancer, cardiovascular diseases, cerebrovascular diseases and diabetes, etc.) accounted for 22.6% of healthcare costs in China, while the cost of lost productivity due to these diseases was about 0.5% of GDP in 1995.

With the advancement of medical technology, the diseases which threaten human life are changing as well. Cancers, cerebrovascular diseases, cardiovascular diseases and respiratory diseases will become the major diseases which threaten human health and life in the 21st century. Medical devices demand analysis is the basis of industrial investment opportunities.

If the incidence or mortality from the disease is low, the demand and frequency of use of the appropriate diagnosis and treatment equipment will be relatively low, the investment payback period for such medical devices will be long for hospitals; in such a scenario, it is difficult for hospitals to recover the cost of medical devices throughout their entire life cycle. So only the large general hospitals will consider purchasing such medical devices. Small and medium-sized hospitals do not have the capacity to buy such equipment. Thus, the market demand for medical devices with low disease incidence is relatively small; investment risk is large and does not have financial investment value. If the incidence or mortality of the disease is high, the demand and frequency of use of the appropriate diagnosis and treatment equipment will be relatively high, the large general hospitals will

be very motivated to purchase such medical devices as well as small and medium-sized hospitals because the investment payback period for such devices will be short.

This study predicts the medical device market demand based on disease profiles and the extent of the medical device market saturation. In a perfectly competitive market, the prices of all products and services in an industry are determined by equating the demand for a good with its supply [31]. In the economics area, there is a principle that as "the price of a good or service rise, the quantity demand falls", this is the price elasticity of demand. However, research reports that the demand for medical technology is extremely inelastic (it does not rely on price) and is free of this principle "competition will make prices fall, narrowing margins and reducing profits" [28]. Other arguments show that the demand for most new products tends to be based on non-price factors [30]. The medical device market has sustainable growth because of the general demographic trends, especially the growth of the aging population and the continued prevalence of diseases [28]. For the Chinese medical device market, the growth of medical services institutions, medical diagnosis and treatment devices, disease profiles and population - especially the aging population, means that the market has great investment potential.

The main medical devices companies' investment activities and/or mergers and acquisitions in China give good indicators of how the market is developing. All these activities contribute to China's medical device industrial growth. Moreover, the Chinese government has developed rural areas healthcare systems in recent years and this investment is continuing, this creates more investment potential for investors. Therefore, foreign investment can make a positive contribution to a host country by supplying capital, management resources and technology that would otherwise not be available and this increases the country's economic growth rate [127, 128]; enhanced technology prowess can stimulate further economic development and industrialization [30]. So, China is a market with fabulous investment potential for health care providers and medical device manufacturers [104]. The strongest fields of foreign investment in the Chinese medical device market include medical imaging (CT, MRI and ultrasound, etc.) and advanced products for treatment of cancers and chronic diseases [35].

As with many studies, this study has several limitations. Appropriate explanatory variables are hard to find, three explanatory variables made the sample size too small to

perform regression analysis. Other market drivers like disease and policy are hard to assess through regression analysis. The market drivers not only include these three drivers; the ownership rate of medical devices and diseases, but also contains other elements. Some of the data from the government report is hard to access, for example: the number and percentage of medical devices in the main hospitals in China, for which data was only reported for the years of 1996, 1998, 2000, 2001 and 2004. The number of medical devices in Chinese hospitals after 2004 is hard to access from the Chinese Ministry of Health database. Despite the data limitations, the chapter describes the Chinese medical device market current situation and identifies the investment potential of the market. The multicollinearity often happens in multiple regression analysis, the adjusted results reported herein are more reliable. Moreover, analysis of the prevalence of diseases shows that cancers are the big challenge for the whole medical area, and that there is an increasing trend in the incidence of death from breast cancer, this indicates that there is a requirement for further research and analysis in this area.

4.5 Conclusion

This study indicates that the Chinese medical device market has great investment potential for identified reasons. China has a rapidly developing economy, there is government investment in the healthcare industry to improve the medical environment, the government is encouraging foreign medical companies to investment in China. Some large foreign companies like GE healthcare, Siemens healthcare and Philips healthcare continue to increase investment in China. This indicates that the Chinese medical device market has significant investment potential for the future. Foreign investment will bring both benefits and risks to the country's health sector [129]. The Chinese medical device market still has room for investment due to the growing aging population and the increasing number of hospital visits. Because China continues to develop economically and socially, the predominance of infectious diseases is decreasing. Chronic diseases (epidemiological transition) are emerging as an increasing problem, hence the healthcare system is experiencing huge pressures from both changing and increasing demands [130].

This chapter provides the first study of its kind in providing a better understanding of the Chinese medical device market. Study suggests that the Chinese medical device market has great potential and shows that medical diagnosis and treatment devices will be in

tremendous demand in the future. The rising numbers of aging people in China, the changed disease profiles and the constant increase in the incidence of chronic diseases like cancers, which requires medical diagnosis and treatment devices such as CT, MRI and ultrasound are driving this demand.

It is noteworthy that China's high-end medical device market relies on imports from the developed countries. These foreign made high-tech medical devices account for 70% of China's medical device market. The number of medical and health institutions increased year by year as did the number of visits and in-patients in healthcare institutions, this huge and increasing demand provides an expanding market for medical devices. Disease profiles determine which kind of medical devices have more investment value in China. Demand analysis indicates that Colour Doppler ultrasound, CT and MRI have great future investment potential. The growth in the aging population is a big test of the health care industry in China, peoples' desire for good health is stronger than before, therefore significant opportunities exist in the medical device market.

Chapter 5 Medical Device Regulations

5.1 Introduction

Unlike ordinary products, medical devices utilise a large number of the latest achievements of modern science and technology and play a significant role in promoting human health. Due to the potential health risks, and the evaluation of the safety and effectiveness of medical devices, many countries have established medical device regulations for their supervision and management. Medical devices must be qualified by passing the safety and effectiveness procedures before they can be marketed in any particular country.

The US was the first country to legally define a 'medical device', and also was the first country to establish a medical device management procedure [131]. As the second largest medical device manufacturers and consumers in the world, the EU also has a rich history of medical device regulations. The US and EU have established relatively mature medical device regulations, which have a key influence in the world. For instance, most of the guidance documents of the Global Harmonization Task Force (GHTF)[14] are based on the US and the EU medical device regulations. China established *Regulations for the Supervision and Administration of Medical Devices* in 2000; these regulations aim to strengthen the supervision and administration of medical devices, ensuring their safety and protecting human health and life. The Chinese State Council released new *Regulations for the Supervision and Administration of Medical Devices* and these came into force on June 1st, 2014. The revisions are intended to create a more scientific and efficient regulatory regime for medical device supervision.

5.2 The United States medical device regulations

In the year of 1938, the US Congress passed the Federal Food, Drug, and Cosmetic Act (the Act). The Act made provisions for medical devices. The US Congress passed the Medical Device Amendments of 1976, which changed the Federal Food, Drug, and Cosmetic Act. These amendments strengthened the supervision and management of

[14] The organization GHTF (was born in 1992) has been permanently replaced by the International Medical Device Regulators Forum (IMDRF) in 2011.

medical devices, and established a classified management regime for medical devices. These amendments and the Safe Medical Devices Act (1990) gave the government administration—U.S. Food and Drug Administration (FDA) the primary authority to oversee and manage medical devices, to make sure that the manufacturers produce safe and effective medical equipment. The medical device regulations can be found in the Code of Federal Regulations-Title 21-Food and Drugs (21 CFR 800-1299) [132] and are enforced by the FDA [133].

The FDA assigns medical devices into one of three regulatory classes based on their risks and the evaluation necessary to describe their safety and effectiveness [134-136]. Class I devices are low-risk such as surgical instruments, medical gloves and stethoscopes, etc. These Class I devices are subject only to "general controls", such as manufacturers registering their name and products with the FDA (Device Establishments); product quality must meet the requirements of the US quality systems (QS) and provide sufficient labelling information. Most Class I devices are exempt from 510(k) premarket notification but must follow the general controls.

Medium-risk Class II devices such as: CT; electrocardiogram devices; absorbable suture etc., must meet the requirements of "general controls" and are also subject to "special controls", such as acceptance of post-market surveillance and additional labelling requirements. These Class II devices usually are required to pass through the 510(k)[15] premarket notification and review-process before the devices enter into the market. The minority of these devices also need to provide some clinical data, via clinical trials, approximately 10% of 510(k) applications include clinical data [137]. In the 510(k) premarket notification process, the manufacturer must provide all the relevant documents and data to the FDA to demonstrate that the new device they produced is at least as safe and effective as a previously cleared (predicate) device (legally U.S. marketed device). This is the *substantial equivalence* (SE)[16] determination by the FDA[138]. Clinical data

[15] A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent to a legally marketed device.

[16] Substantial equivalence means that a new device is at least as safe and effective as the predicate device, which

- has the same intended use; **and**
- has the same technological characteristics; **or**
- has the same intended use; **and**
- has different technological characteristics and the information submitted to FDA; (1) does not raise new questions of safety and effectiveness; **and** (2) demonstrates that the device is at least as safe and effective as the legally marketed device.

may be necessary to prove that the new device is "substantially equivalent" to a 510(k) device [137]. The new device cannot legally enter into the market without SE. If the new device was determined as substantially equivalent, additional clinical data is not usually required [139], but performance standards, patient registries and post-market surveillance may be imposed [134, 137]. If the FDA decides that a device does not qualify for SE, the applicant may: resubmit another 510(k) with new data; request a Class I or Class II designation through the *de novo*[17] process; file a reclassification request or submit a premarket approval application (PMA) [138].

High-risk Class III devices are used to support and sustain human life; they may be implanted into the human body permanently, playing a vital role in human health, such as: a prosthetic heart valve; pacemaker or artificial blood vessels, etc. For these devices general and special controls are insufficient for the assurance of their safety and effectiveness [137], hence they require the most strict controls, therefore the formal review process PMA will be imposed. PMA requirements apply to Class III devices, the most stringent regulatory category for medical devices [140]. Most Class III devices require PMA before they can be legally marketed. The manufacturer must supply the scientific report and clinical data to the FDA to illustrate that the device is safe and effective for its intended use. If the new device does not have a predicate device, it will be classified as Class III automatically, regardless of its risk level. But if the device is classified as low- or medium-risk, the manufacturer can apply for reclassification to Class I or Class II devices through the *de novo* process and do not go through the PMA process [135]. If the new Class III device has little changes to the former PMA-approved device, the manufacturer may not need to provide more clinical studies [141, 142], but some selected Class III devices are subject to post-market surveillance [137].

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. Investigational use also includes clinical study of certain modifications or new intended use of legally marketed devices [143]. All clinical study of investigational devices, unless exempt, must submit an IDE and be approved by the FDA before the study is initiated. An approved IDE

[17] The *de novo* is a risk-based and evidence-based classification process, which provides a pathway to classify a low- or medium-risk device for which general controls or special controls provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed device. Devices are that classified into Class I or Class II through the *de novo* process may be marketed and used as predicates for future 510(k) submissions.

permits a manufacturer to collect sufficient data from the clinical trials to support the marketing submission (small percentage of 510(k) and PMA) [144]. FDA allows a manufacturer with an approved IDE to conduct clinical trials of investigational devices without complying with other requirements that would apply to devices in commercial distributions. For example, a manufacturer need not register its product, submit a 510(k) or PMA. In addition, an approved IDE is also exempt from the Quality System Regulation except for the requirements for design controls. Good Clinical Practices (GCP) refers to the regulations and requirements that must be complied with while conducting a clinical trial. These regulations apply to the manufacturers, sponsors, clinical investigators, institutional review boards, and the medical devices [143].

Moreover, the humanitarian use device (HUD)[18] is exempt from the effectiveness requirements of a PMA, called humanitarian device exemption (HDE) [145]. To obtain approval for an HUD, an HDE application is submitted to the FDA. An HDE is similar in both form and content to a PMA, but is exempt from the effectiveness requirements of a PMA. But the application must contain sufficient information to show that the device does not pose a risk. In addition, the applicant must describe that no comparable devices are available to treat or diagnose the disease. The cost of these kind of devices' R&D will exceed their market returns for the manufacturers. The HUD provision provides an incentive for manufacturers to conduct R&D into these devices.

The statutory mission of the US FDA is to protect public health and aims to ensure that all marketed medical devices are safe and effective [146]. The FDA requires mandatory medical device reporting (MDR) for post-market surveillance. Manufacturers, device users and importers must report the device-associated deaths, serious injuries and malfunctions. The FDA also encourages patients or any other medical device related people to report any serious adverse events that may be associated with a medical device, and quality issues, use errors, etc. [147]. All these actions are taken by the FDA to protect and promote public health.

[18] An humanitarian use device is for very low prevalence patients (no more than 4,000 individuals in the US per year) diagnosis and treatment.

5.3 The European Union medical device regulations

Until the 1990s, in the area of medical devices, the EU enacted three directives to replace each member state's regulations. The directives harmonised the EU medical devices market, ensuring medical device safety and a high level of protection for human health and effective functioning of the "single market". As a part of the single market program, the EU enacted three directives in the medical devices field, namely: Active Implantable Medical Devices Directive (AIMDD, 90/385/EEC); Medical Devices Directive (MDD, 93/42/EEC) and In Vitro Diagnostic Medical Devices Directive (IVDMDD, 98/79/EC) [148]. The EU directives set out "Essential Requirements" for the approval process for medical devices; any product (including medical device) that conforms to EU requirements will be Conformité Européen (CE)-marked [29] (Figure 5-1). Only CE-marked medical devices can be sold in the market. According to these directives, medical devices are categorized into four-classes (Classes I, IIa, IIb, III) based on the risk level associated with the technical design and manufacture of the devices [149].

Figure 5-1 The CE mark.

Class I are low-risk devices, these only require self-declaration conformity with the essential requirements of a Competent Authority[19] governmental body, without any need to refer to the Notified Bodies[20] or any involvement with them [134, 135]. The intervention of a Notified Body is for approval for medium and high risk medical devices (Classes IIa, IIb, and III). The manufacturer is responsible for Class IIa device's design, the Notified Body will verify the device quality and assess the conformity at the production stages. Conformity assessment and Notified Body verification of Class IIb and Class III are vital procedures at both the design and production stages [137]. In

[19] Competent Authority such as the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK; Federal Institute for Drugs and Medical Devices (BfArM) and Paul Ehrlich Institute in Germany, etc.
[20] A Notified Body is usually a third-party, independent, private commercial company that assess and inspect whether a product (including medical device) meets the EU standards, for CE marks.

addition, the Notified Body will not only verify Class IIb device's quality but also the manufacturer must provide the design documents to the Notified Body. Besides conformity assessment, Notified Body verification and design documents submission, the Notified Body will examine Class III device's risk analysis report. The Notified Body examination results will be reported to the Competent Authority and the European Commission. Although clinical trial evidence is a stringent requirement for Class III devices, the evidence requirements are vague, and not available to the public [134, 135, 150]. Moreover, if the device performs as intended, in which the benefits outweigh the expected risks, the standard is met [134, 151]. In the quality systems, the standard adopted by the European Committee for Standardization (CEN) is EN ISO 13485 [21] is harmonized with the EU Medical Device Directives 93/42/EEC. The Notified Bodies will certificate the quality of the devices, and also assess the performance of high-risk devices in their laboratory. Any device that passes the quality certification will obtain the CE mark and can be sold within the EU. Compared with the US medical device regulation, the EU regulatory regime is designed to access the device's safety and performance (that a device functions as intended or is 'fit for purpose') rather than effectiveness, as in the US [29, 135].

When the devices enter into the European market, the Member States are required to establish the vigilance procedure for post-market surveillance [152]. The vigilance system requires that the Competent Authorities, Notified Bodies, manufacturers, users and other related authorized representatives jointly monitor the system. Manufacturers are required by law to report all serious adverse events (involving devices they produce or sell or recall a device for technical or medical reasons) to the Competent Authorities [153, 154]. Each Competent Authority has rights to access to the European Databank on Medical Devices (EUDAMED), which is not publicly accessible. EUDAMED contains data on manufacturers, authorized representatives and devices; certificates issued, modified, supplemented, suspended, withdrawn or refused; clinical investigations, which use is obligatory since May 2011 [155]. The purpose of EUDAMED is to enhance market surveillance and transparency in the medical devices area by providing Competent Authorities with quick access to information as well as to contribute to a uniform

[21] ISO 13485 is an International Organization for Standardization (ISO), requiring a quality management system for the design and manufacture of medical devices.

application of the Directive [156]. The Member State shall immediately inform the Commission or EUDAMED of any activities, which constitute non-compliance with the Directive requirements [157].

5.4 The Chinese medical device regulations

In recent years, the Chinese government issued many medical device related policies, involving the most important things are healthcare reform and medical device regulations. The Chinese government healthcare reform will effectively boost the demand for medical devices; while more stringent medical device regulations would demand a higher requirements of medical device safety and production, to make the Chinese medical device market become more standardized. Companies interested in entering the Chinese market should realize they must overcome existing barriers and the changing regulatory environment.

5.4.1 The old medical device regulations

There is little research into the Chinese medical device regulations because compared with the relatively mature US and EU regulations, the Chinese regulations are evolving with the new regulations just released, hence there is a requirement for more research in this area. In this chapter, we describe the differences between the "Old Regulations" and the "New Regulations". Generally speaking, the new regulations moderate the supervision on low-risk devices and strengthens the oversight of high-risk devices.

Relatively speaking, the Chinese medical device regulations were established late. In 2000, *Regulations for the Supervision and Administration of Medical Devices* were established, the regulations laid down the legal status of medical devices' supervision and management. This was the first edition of the regulations and was a milestone in China's medical device regulation history. The "Regulations" gave the China Food and Drug Administration (CFDA) authority to oversee medical devices and ensure their safety and effectiveness, and protect human health and life.

China's definition of a medical device can be found in the *Regulations for the Supervision and Administration of Medical Devices, 2000* [158]. Medical devices are defined as:

Any instrument, apparatus, material, or other article whether used alone or in combination, including the software necessary for its proper application. It does not achieve its principal action in or on the human body by means of pharmacology, immunology or metabolism, but which may be assisted in its function by such means; the use of which is to achieve the following intended objectives:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease;
2. Diagnosis, monitoring, treatment, alleviation of or compensation for injuries or handicap conditions;
3. Investigation, replacement or modification for anatomy or a physiological process;
4. Control of conception.

Similar to the US medical device regulations, the CFDA classify medical devices into three classes [158]. Class I devices are those for which safety and effectiveness can be ensured subject to routine administration (general controls) and do not need clinical trials; Class II devices need further controls (special controls) to ensure their safety and effectiveness; Class III devices are subject to strict controls because these kinds of devices may be implanted into the human body, or be for life support, they have the potential to put the patient's life at risk. The Chinese medical device registration system is different from the US system and EU system. In China, Class I devices are inspected and approved by the city's CFDA (city level). The province's CFDA (province level) are responsible for Class II devices' inspection and registration certificate. All the Class III devices are controlled by the State/central CFDA (national level) [159]. Most Class I devices can be registered for production directly but must follow general controls. Class II and III devices' registration are not only subject to special and strict controls, but also requires clinical trial evaluation before they are put into production. Furthermore, when importing medical devices into the Chinese market for the first time, no matter what the class level is, the central CFDA will be responsible for the device's supervision and administration. The importer needs to provide details of the devices' intended use, quality standards, testing methods, product sample and other relevant documents for the central CFDA oversight.

Medical devices in China are covered by China National Standards (GB standards) and professional/industry standards (YY standards) [160]. Medical devices must at least meet the requirements of the Chinese GB standards or YY standards, or meet other standards like ISO or equivalent if the devices want to sell in the Chinese market. Some medical

devices still need the China Compulsory Certification (CCC) mark for product safety, such as medical diagnostic X-ray equipment, electrocardiograph, pacemaker, etc. [67].

China established the adverse events monitoring system and information networks, medical devices re-evaluation and medical device recalls but these systems are still under construction and need more legislative support.

The mission of the CFDA is: public health protection and to ensure that all the marketed medical devices are safe and effective. The CFDA usually carries out random testing for medical devices' manufacturers and users. The CFDA has established the adverse events systems to collect all the information on medical devices surveillance, this encourages medical devices related people to report any medical devices relevant information, like quality issues and serious injuries or deaths of patients [161].

5.4.2 The new medical device regulations—major changes

The Chinese State Council released the new *Regulations for the Supervision and Administration of Medical Devices* in 2014, which was the second edition of the medical device regulations. Compared with the old regulations (48 articles), the new ones have 80 articles and many changes on device registration; clinical trials; adverse events; recalls, etc. The new regulations are consistent with the goal of the "National 12th five-Year Plan" to foster innovation and encourage domestic companies' R&D while enhancing the protection of public health [162]. The government overhauled the regulations in order to catch up with the fast development in the medical device industry and economy.

According to the new regulations, the revised definition of medical device is [163]:

Any instrument, apparatus, appliance, in-vitro diagnostic reagent and calibrator, material, or other articles alike, including the necessary software, directly or indirectly used on human body, which functions by means of physical ways, instead of by means of pharmacology, immunology or metabolism, or the participation of pharmacology, immunology or metabolism means only plays an assistive role; the use of medical devices is to achieve the following expected purposes:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease;
2. Diagnosis, monitoring, treatment, alleviation of or compensation for injuries or handicap conditions;
3. Investigation, replacement, modification or support of a physiological structure or process;

4. Supporting or maintaining of life;

5. Control of conception;

6. Providing information for treatment or diagnosis purpose by inspecting the samples from human body.

<1> *Classification of medical device*

The new regulations classify and administer medical devices based on their risk levels. Class I medical devices are those with a low-risk level, which through routine administration their safety and effectiveness can be ensured; Class II medical devices are those with a middle-risk level, for which strict control and administration is required to ensure their safety and effectiveness; Class III medical devices are those with a high-risk level, for which special measures and strict control shall be taken to ensure their safety and effectiveness. Compared with the old regulations, the new regime introduces risk management into the regulations. Risk management not only in the device classification sections, but also in other parts. For example, "medical device registration should submit a risk analysis report of the product; medical device recalls and adverse events".

<2> *Medical device regulation*

According to the new regulations, Class I devices will no longer require registration, but will change to record-filing. The applicant shall submit the required documents to a city CFDA (same as the old regime) for the device record-filing procedure. The applicant shall submit the following materials to the regulatory authority for Class I devices record-filing; Class II and Class III devices registration: (1) Risk analysis report of the product; (2) Technical requirements of the product; (3) Testing report of the product; (4) Clinical trial materials; (5) Product instructions for use and sample label; (6) Quality management system documentation related to R&D and manufacturing of the product; (7) Other documents which prove the safety and effectiveness of the product. Moreover, the applicant for the medical devices record-filing or registration shall be responsible for the authenticity of the submitted documents [164].

Like the old regulations registration procedure, Class II devices are administered by a provincial CFDA and Class III devices are administered by the central CFDA. Class I devices do not require clinical trials for the record-filing procedure, Class II and Class III devices require clinical trials for registration. However, clinical trials can be exempted in

any of the following circumstances: the device is at least as safe and effective as a previously cleared (predicate) device (legally Chinese marketed device), which has similar intended use and no severe adverse events record; a medical device which proves to be safe and effective through non-clinical evaluation assessments; a medical device which proves to be safe and effective through the analysis and evaluation of the data obtained from clinical trials or clinical application of the substantially equivalent medical devices. In addition, the duration of the medical device registration certificate is five years (the old regulations suggest the registration certificate must be renewed every four years).

<3> *Medical device production*

The new regulations pay more attention to Good Manufacturing Practices (GMPs) for medical device production management. GMP is that part of quality assurance, which ensures that medical products are consistently produced to the required product specification and controlled to the quality standards appropriate to their intended use. GMP is concerned with both production and quality control [165].

The CFDA requires that all the medical devices in the Chinese market should be accompanied with product specifications and labels. In addition, the new regulations require Class II and Class III devices should also indicate the registration certificate number and register's affiliations with product specifications and labels. Moreover, if the medical device can be used by the consumer independently, the product specifications and labels should include special instructions for its safe use.

According to the new regulations, if a medical device is within a manufacturing consignment, the consigner shall be responsible for the quality of medical devices. The consignee shall be a medical device manufacturer which meets the CFDA's requirements. In addition, the embedded medical devices with a high-risk level shall not be manufactured in consignments [166].

<4> *Distribution/operation and use of medical devices*

The old regulations required companies who distribute/operate Class I medical devices to file records with the provincial CFDA. Companies distributing/operating Class II and Class III medical devices need to obtain the Medical Device Distributing Enterprise License, which is issued by the provincial CFDA. The New Regulations removes record-

filing for Class I device distributors and requires Class II device distributors to file records with the provincial CFDA.

The new regulations also place more obligations on medical device distributors and users. Such obligations cover all aspects of using medical devices including device supplier's certificates, quality certificates, records of purchase/sales, transportation and storage, operator technical training. Moreover, the medical device user shall inspect, verify and maintain the devices periodically to ensure the devices are in good condition, safe and effective.

Imported medical devices shall be accompanied with product specifications or user manuals and labels in Chinese, and specify the devices' place of origin and agent's affiliations. The medical device exporters shall ensure the exported devices comply with the requirements of the importing countries.

<5> *Medical device adverse events and recalls*

The old regulations were silent about medical device adverse events and recalls. However, the central CFDA and the Chinese Ministry of Health (MOH) issued provisional Decree 425 for tracking adverse events [167] and provisional Decree 82 for managing medical device recalls [168] in 2011, respectively.

The new regulations issued requirements on monitoring medical device adverse events and managing recalls. These requirements set clear responsibilities from device manufacturer personnel to distributors and patients/consumers. The central CFDA established the medical device adverse events monitoring system and information networks to: collect information, analyse, evaluate and control adverse events in a timely manner. Any medical device manufacturer, distributor and user has rights to report adverse events to this monitoring system and information networks, and the CFDA will also collect adverse events information proactively.

The new regulations require the device manufacturer to stop production if the device does not meet the compulsory standards or contains other defects, furthermore, they must notify relevant distributors or users to stop distributing or using this kind of device and recall the devices which are already on the market. According to MOH Decree 82, there

are three levels of recalls based on the severity of medical device defects [168]. Level I recalls means that if use of the medical device has caused, or may cause, serious health hazards that are of a permanent nature; Level II recalls means use of the medical device may cause health hazards that are of a temporary or permanent nature; Level III recalls mean use of the medical device may not be likely to cause harm but it is still defective [67].

<6> *Supervision and inspection*

The new regulations require that the CFDA enhance supervision and inspection of medical devices' registration, record-filing, production, distribution and use, sometimes using random checks. The provincial CFDA or central CFDA will issue medical device quality circulars based on the results of timely random checks.

The central CFDA has established a shared medical device supervision and inspection information network. The CFDA should legally and in a timely manner publish the medical devices' license, record-filing, random check results and illegal behaviour through the information network. In addition, the CFDA also established the credit files for medical device registrants, record-filing applicants, manufacturers, distributors and users, and increased the frequency of inspection upon those who have a poor credibility record. Moreover, the CFDA publish their contact information for inquires, complaints and reports. Information disclosure is a major breakthrough for the Chinese medical device market participants' supervision and inspection.

<7> *Legal liabilities*

The new regulations have increased sanctions and penalties for various violations. For example, administrative penalties up to 20 times (5 times in the old regulations) the value of the manufactured products may be imposed on medical devices produced without the proper permits. In some severe circumstances, relevant personnel and companies will be suspended from application for any medical device permits or licences for 5 years, and may be subject to criminal sanctions if such violation constitutes a criminal offense. Penalties or criminal offenses may be incurred for the following actions: permits (medical device registration certificate, production permit, distribution permit, advertisement approval certificate) are obtained by providing false information or by using other methods of cheating; relevant medical device permits or certificates are forged, altered,

transferred, leased and lent; manufacture, distribute or use of devices which are not compliant with the compulsory standards or technical requirements; any clinical trials conducted in violation of the Regulations or medical device clinical trial institutes issuing false reports, etc.

5.4.3 New regulations versus old regulations

Table 5-1 Comparison of the Chinese medical device regulations.

	Category	New regulations (2014)	Old regulations (2000)	Comparison
1	Classification	Classify and management of medical devices according to their risk levels.	Classify medical devices and administer them based on the classification.	Main changes: the classification of medical devices, which introduced risk levels into the rules.
		Class I medical devices are low-risk and safety and effectiveness can be ensured through routine administration (general controls).	Class I medical devices are those for which safety and effectiveness can be ensured through routine administration (general controls).	
		Class II medical devices are medium risk and further control (special controls) is required to ensure their safety and effectiveness.	Class II medical devices are those for which need further controls (special controls) to ensure their safety and effectiveness.	
		Class III medical devices are high risk devices subject to strict controls to ensure their safety and effectiveness.	Class III medical devices are implanted into human body, or used for life support, need strict controls.	
		To evaluate the risk levels of medical devices, shall consider medical devices' expected objectives and user instructions, etc.	n/a	
		Class I medical devices shall be subject to record-filing and do not need clinical trials; Class II and Class III devices require registration, need clinical trials.	Class I, Class II and Class III devices all require registration. Class II and Class III devices need clinical trials.	Simplified the application procedure of Class I medical devices.

2	Registration	Class I devices record filing, Class II and Class III devices registration need to submit: (1) Risk analysis report of the product; (2) Technical requirements of the product; (3) Testing report of the product; (4) Clinical trial material; (5) Product instructions for use and sample label; (6) Quality management system documentation related to R&D and manufacturing of the product; (7) Other documents which prove the safety and effectiveness of the product.	No detailed requirements.	The new regulations proposed the detailed submission materials for devices record filing and registration.
		Registration order: apply for registration certificate first, then apply for manufacturing license.	Registration order: apply for manufacturing license first, then apply for registration certificate.	The advantages of the changes: Companies do not need large initial investments before they get a registration certificate. Ensure companies focus on products R&D. After got the registration certificate, companies can invest more into production.
		Medical device registration certificate shall be valid for 5 years. If the registration certificate needs renewal, an application shall be filed with the original	The term of validity for the registration certificate is 4 years. The registration certificate need to be renewed within 6	

		registration department 6 months prior to expiration date. If the CFDA review is not completed by the certificate expiry date, automatic renewal is granted. However, renewal will not be granted if applications are not lodged in time or devices do not meet the compulsory standards.	months before certificate expires. When companies continuous stop production for more than 2 years, their registration certificate will automatically invalidated.	
		Applying for medical device registration: The CFDA shall transfer application materials to technical review institutions within 3 working days after acceptance of the application; The technical review institutions shall submit review opinions to the CFDA after technical review; The CFDA needs to make decisions within 20 working days from the date when received the review opinions.	Applying for medical device registration: City's CFDA shall make decisions within 30 working days from the date of application; Province's CFDA shall make decisions within 60 working days from the date of application; Central/State CFDA shall make decisions within 90 working days from the date of application.	The new regulations shorten the review time, improved the efficiency. Class I devices need record-filing with city's CFDA; Class II and Class III devices need to register with province's CFDA and central CFDA, respectively.
		Uncategorized devices may apply using Class III pathways, or according to the classification rules to determine the products categories, to apply for classification to the CFDA, then record-filing or registration.	n/a	
		Device manufacturers shall have: Production site, environmental conditions and professional technical personnel; quality testing staff and institutions;	Device manufacturers shall have: Professional technical personnel; facilities/factories and environmental conditions; manufacturing equipment;	The new regime require manufacturers to have a quality management system.

		quality management system; after-sales service; R&D and production process documents.	quality testing staff and institutions.	
3	Production	Medical device manufacturing/production license valid for 5 years; If a license needs renewal, the CFDA will in accordance with relevant laws and rules renew the license.	Manufacturing/Production license valid for 5 years. Upon expiration, re-inspection and license renewal shall be conducted.	Renewal of the existing license, the new regulations require no further reviews and re-inspection.
		The new regulations proposed medical device manufacturers must follow the requirements of device quality management, to ensure their products meet the Chinese GB standards or YY standards or other standards such as CCC. Moreover, manufacturers must ensure that the technical requirements of their products consistent with the records they submitted to the CFDA.	n/a	The new regime introduce quality management system into device production and quality control.
		The new regulations require detailed devices' instructions and labels; Class II and Class III devices also need to contain registration certificate number and register's affiliations.	No detailed requirements.	
		Class I device operators are not required to file records and license; Class II device operators need to file records with the city's CFDA; Class III device operators need to apply for an operating license with the city's CFDA.	Class I device operators need to file records with the province's CFDA; Class II and Class III device operators need to apply for an operating license with the province's CFDA.	The new regulations improve the efficiency of medical device operation.

4	Operation	Medical device distributing/operating license valid for 5 years; If license needs renewal, the CFDA will in accordance with relevant laws and rules renew the license.	Distributing/Operating license valid for 5 years; Upon expiration, re-inspection and license renewal shall be conducted.	Same method with manufacturing license renewal, the new regulations require no further reviews and re-inspection for operating license renewal.
		Require device operators establish sales/purchase record system, especially Class II and Class III devices. Records must include: (1) device name, model, specification and quantity; (2) device serial number, validity and sale date; (3) name of device manufacturer; (4) device supplier or buyers' detailed contact information; (5) related documentation and license; (6) Class III devices provide key technical parameters information.	n/a	
		Imported devices should have instructions and labels in Chinese, specify the devices' place of origin and agents' affiliations.	n/a	
		Companies should ensure that their devices exported to other countries, should meet the requirements of the importing countries.	n/a	
		The medical device manufacturers, operators and users should monitor adverse	No detailed requirements.	The old regulations were silent about adverse events and

5	Adverse events and recalls	events, report any adverse event to the CFDA timely.		recalls, but using the supplementary decrees to oversight the medical device adverse events and recalls. The new regime added adverse events and recalls to the regulations.
		The CFDA established the medical device adverse events monitoring system and information networks to collect adverse events information and control adverse events.	No detailed requirements.	
		Device manufacturers or users found that their products do not meet the mandatory standards or are flawed, need to stop using the devices and recall the devices or report to the CFDA.	No detailed requirements.	
6	Supervision and inspection	The CFDA must focus supervision and inspection on: (1) whether the device manufacturers' production is in accordance with the technical requirements they submitted to the CFDA; (2) whether the device manufacturers' quality management system operates effectively; (3) whether the device manufacturers and operators' production and operation conditions still continued compliance with the statutory requirements.	No detailed requirements.	The new regulations clearly defined the contents of supervision and inspection: technical indicators and quality management system.
		The CFDA staff have the following rights for oversight: (1) access to the manufacturing site for inspection and take samples;	No detailed requirements.	The new regulations strengthened the CFDA's supervision, refined contents of oversight.

		(2) read, copy and confiscate contracts, bills or other related documents; (3) close down, confiscate devices or production site which have not met the statutory requirements.		
		The central CFDA established a unified information platform for the supervision and management of medical devices. City's CFDA and province's CFDA should promptly publish supervision information through the unified information platform, but cannot disclose commercial secrets.	No detailed requirements.	The new regulations advocate information disclosure, which increased the transparency of the supervision.
7	Legal liabilities	Value of the illegally manufactured devices not exceeding 10,000 yuan, will be subject to a fine of 5 to 10 times of 10,000 yuan; value of the illegally manufactured devices exceed 10,000 yuan, will be subject to a fine of 10 to 20 times of the devices value.	Illegal gains from the illegally manufactured devices not exceed 10,000 yuan, will get 10,000 yuan to 30,000 yuan penalties; illegal gains exceed 10,000 yuan, will get a fine of 3 to 5 times of illegal gains.	The new regulations increased sanctions and penalties for various violations. Moreover, the new regime increased penalties for dishonesty.
		In some severe circumstances, relevant companies will be suspended from application for any device license or permit for 5 years, and may be subject to criminal sanction: (1) manufacturing or distributing Class II and Class III devices without licenses or permits; (2) be licensed through providing false information or deception;	n/a	

		(3) clinical trials illegally.		
		Any personnel and company advertising false medical devices to the public, will get 20,000 yuan to 50,000 yuan penalties; Any personnel and company tampering with approved advertising content, will be suspended from application for medical device advertisement for 2 years.	No detailed requirements.	

The CFDA issued the new *Measures for the Administration of Medical Device Registration; Measures for the Administration of In Vitro Diagnostic (IVD) Reagents Registration; Provisions on the Administration of Manuals and Labels of Medical Devices; Measures for Supervision and Administration of Medical Device Production* and *Measures for Supervision and Administration of Medical Device Operation* that came into force on the 1st October, 2014. The new *Measures for the Administration of Medical Device Registration* outlines the timeline from application acceptance to certificate delivery for medical devices (Figure 5-2).

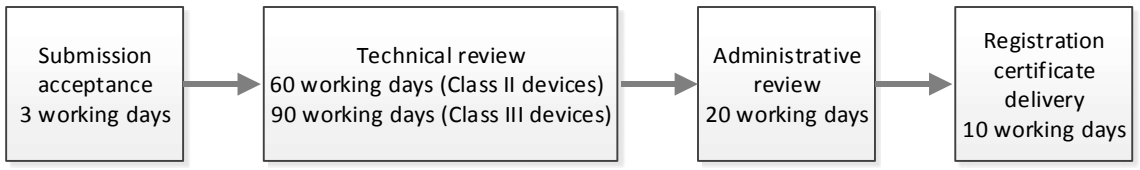

Figure 5-2 Timeline of medical device registration.
Note: excludes time spent in responding to review questions or expert committee reviews.

The timeline of medical device registration shows that Class II devices need at least 93 working days to get the medical device registration certificate from the province's CFDA and Class III devices need at least 123 working days to get the registration certificate from the central/state CFDA. Class I devices only need filing with the city's CFDA. The timeline of medical device registration in the old guidance illustrated that the administrative reviews and issue a decision for the registration certificate needed at least 30 working days (Class I devices); 60 working days (Class II devices) and 90 working

days (Class III devices), respectively. The new medical device regulations and new registration guidance show that the CFDA is moving towards a simplified registration review process for low risk/Class I devices so that resources can be directed to supporting the high risk devices regulatory review [169].

The new guidance *Measures for Supervision and Administration of Medical Device Production* outlines the timeline from submission acceptance to certificate delivery for the Class II and Class III medical device manufacturing/production licenses, which need at least 40 working days (30 working days for administrative reviews and issue of a decision; 10 working days for license delivery) from the province's CFDA. Class I device manufacturers need to complete record-filing with the city's CFDA to obtain the production licenses. The medical device manufacturing/production license is valid for 5 years. This provision is only for domestic manufacturers.

The new guidance *Measures for Supervision and Administration of Medical Device Operation* outlines that Class I device operators do not need to file records and license; Class II device operators need to file records with the city's CFDA; Class III device operators need to apply for an operating license from the city's CFDA. The timeline from application acceptance to certificate delivery for the Class III medical device operation licenses, which need at least 40 working days (30 working days for administrative reviews and issue of a decision; 10 working days for license delivery) from the city's CFDA. The medical device operation license is valid for 5 years.

The CFDA issued the new *Rules for Medical Device Classification* in 2015 that came into force on the 1st January, 2016. The CFDA uses "classification rules" and "classification catalogues" to implement medical devices classification. The new *Medical Device Classification Catalogues* are still under revision. The "classification rules" are the guide to make "classification catalogues" and provides the identification of a new device registration category.

The CFDA also issued the new *Provisions on the Administration of Manuals and Labels of Medical Devices* to control medical device labelling. The new provisions have 19 articles, which mainly specify the requirements of device manuals and labels for medical device safety. The new provisions require both domestic devices and imported devices

should have manuals and labels for the Chinese version. The manuals and labels of imported devices could contain other languages but reviews are based on the Chinese version description.

5.5 Comparison of medical device regulations

The US, EU and Chinese approaches to medical devices regulation are different. In this section we will compare aspects of registration, classification, premarket and post-market controls between the US, EU and China.

<1> *Registration*

The US FDA is open to all medical devices related companies for all medical devices (Class I, II and III) registration, whereas only manufacturers can register medical devices in China; if the devices are imported, their Chinese agents need to register the devices. The EU medical device registration system is similar to the US FDA's. Manufacturers and other related medical companies need to register their devices with the Competent Authorities.

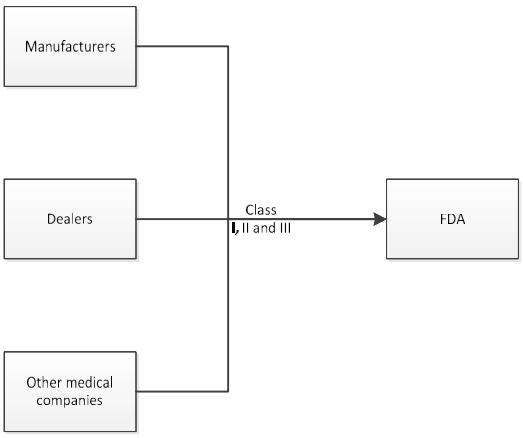

Figure 5-3 FDA registration system.

Centralization of the US FDA registration system (Figure 5-3) provides consistent evaluation criteria. Class I devices are low-risk and subject only to general controls, manufacturers can register their devices with FDA; Class II devices are medium-risk, which require special controls. The majority of these devices usually are required to pass through the 510 (k) premarket notification process before enter into the market; high-risk

Class III devices require strict controls and have to pass through the formal review process—PMA.

Some experts suggested that the 510 (k) clearance process should stop and be replaced with an evaluation of device safety and effectiveness process [170], greater centralization leads to a strict, time-consuming and costly regulatory process [171, 172]. Moreover, the Institute of Medicine recommended the FDA should eliminate the 510 (k) premarket notification process because it was ineffective and unsalvageable [173]. The current FDA system has been simultaneously faulted for inadequate assurance of safety and efficacy [174]. In addition, both the US FDA and EU authorities require device manufacturers to prove the safety of their products, the FDA still need to certificate the new products' effectiveness (perform better than already marketed devices) rather than the 'performance (fit for purpose)' of the EU regulation, which means the EU system is relatively faster than the US. However, a centralized system provides searchable listings for the public and has a database of serious adverse events and post-market reports, these resources are useful to independent researchers evaluating specific medical devices [134, 175-177].

Different from the centralized FDA registration system, the EU system relies on 74[22] decentralized designated agencies—Notified Bodies. The decentralization of the EU system provides the governmental Competent Authorities with the high working efficiency and a fast review process compared with the FDA. However, the decentralized system also has disadvantages. Different Member States have inconsistent levels of technological development, this makes it difficult to guarantee the Notified Bodies' staff or reviewers have consistent knowledge, cognitive level and inspection standards, which means there may be inconsistency in the process for approving similar medical devices among Notified Bodies [178]. Manufacturers can choose the Notified Body that they put their devices through and can select the Notified Body with the least rigorous reviews [179], which permits them to identify the easiest route to getting the CE mark [134]. In addition, decentralization also inhibits the collection of safety data for patients to detect the potential problems and identify the adverse events [180].

[22] Number of 74 Notified Bodies, updated until June 2014. Refer to the European Commission website: http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13

The Chinese registration system is a hierarchical system (Figure 5-4). This system theoretically should have a short processing time and high efficiency. The CFDA has local regulatory agencies, which includes 31 provincial, 433 municipality and 1,936 county-level agencies. Technical organizations include 16 state, 122 provincial, 373 municipal and 436 county-level organizations [181]. The regulatory agencies (except county-level), which can issue a medical device registration certificates.

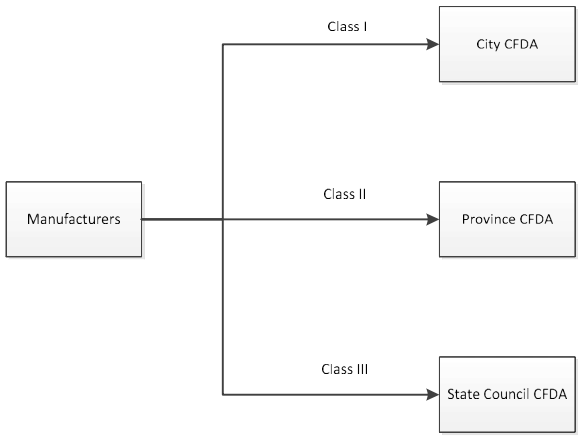

Figure 5-4 CFDA registration system.

Similar with the US FDA's pathways to approval, the new pathway of the CFDA requires low-risk Class I devices record filing with the city CFDA for premarket approval; medium-risk Class II devices should register with the province CFDA and high-risk Class III devices register with the central CFDA. Both Class II and Class III devices require a more in-depth technical review for approval. Moreover, Class I devices do not require clinical trials; Class II and Class III devices require clinical trials, some devices may be exempted from clinical trials if included in the *List of Exempted Devices*. Devices not listed may also apply for exemption if the devices are substantially equivalent. In addition, medical device registration certificate renewal must be submitted at least 6 months prior to the expiration.

<2> *Classification*

The US FDA has established classifications for about 1,700 distinct types of medical devices and organized them into 16 medical speciality "panels" such as cardiovascular devices or ear and nose devices. These panels can be found in 21 CFR Part 862-892 [136, 182]. These actions ensure that all the devices on the US market have scientific and

unique names. If a device cannot find a predicate device on the market, or due to some reasons needs reclassification, the FDA staff will review and evaluate the device's safety and effectiveness. The FDA has a rigorous classification review process to ensure the medical devices are safe and effective and promotes good public health. The Class I and Class II devices accounted for 90% of medical devices in the US market, from which 47% of medical devices fall under Class I and 43% fall under Class II. 10% of medical devices fall under Class III (Table 5-2). In addition, about 95% of Class I devices and a small number of Class II devices (about 8%) are exempt from the premarket notification process [183].

Table 5-2 Percentage breakdown of medical devices classification levels.

Country/Class	Class I devices	Class II devices	Class III devices
US	47%	43%	10%
EU	23%	64%	13%
China	36%	41%	23%

The EU directives classify medical devices into four categories: non-invasive devices (Rule 1-4); invasive devices (Rule 5-8); active devices (Rule 9-12) and the Special Rules (Rules 13-18) [184]. Due to the large number of medical products, the EU four levels of classification system is considered more reasonable. The GHTF adopted the EU classification methods as their guidance documents: 'Principles of Medical Devices Classification' [185]. Table 5-2 shows the comparisons of different medical devices classifications.

The Chinese medical device classification criteria are similar to the US's. The CFDA classify the devices into three classes. There are no more than 5,000 types of medical devices in the Chinese market, but there are more than 60,000 devices that have the registration certificate issued by the CFDA regulatory agencies [186]. The reason for this is that under the old standard, the naming of devices was inconsistent, this results in the same products having different names, or the same names may be different products. In contrast, in the US, one device can only have one name and one product code; different products have different names and codes. The US FDA device classification system is a database system associated with an expert group providing technical support; the EU devices classification system is based on the 'Directives Rules'. The CFDA uses the

devices ‘classification rules’ and ‘classification catalogues’ to implement the medical devices classification. For instance, when a device needs to be classified, the reviewers will first look at classification catalogues, if the product does not appear in the catalogues, the reviewers will classify the device according to the classification rules. In addition, only about 8%-10% of medical devices are classified as high-risk devices in the US whereas more than 20% of devices are classified as high-risk devices in China, see Table 5-2. For instance, the CT scanner was classified into Class II devices in the US [187, 188], while it is classified into Class III in China [189]. Many products are classified as high-risk devices in China. This not only brings a heavy economic burden to the manufacturers, but also creates high cost and low efficiency for the government management. The US FDA pays more attention to review 10% high-risk Class III devices because they are usually the new products using new technology. In China, Class III devices accounted for 23% of the total devices, but, high-risk and innovative products do not exceed 5% of total applications for registration [190].

<3> *Premarket controls and post-market surveillance*

The US and EU device authorities are fully aware of the importance of the ‘Standards’, so the authorities cooperate with ISO for the latest knowledge and information. The EU directives established the legal status for the ‘Standard’, made the ‘Standard’ requirements as the key basis for devices safety review. CFDA established its own Standards system in China, such as national standards (GB standards) and professional standards (YY standards). Moreover, due to the complex and diverse products, devices premarket controls need more technical support. The US and EU have relatively mature and adequate technical support, for example, the Device Committee in the EU and three centres in the US, for the devices oversight (Center for Devices and Radiological Health; Center for Biologics Evaluation and Research; Center for Veterinary Medicine) [191]. Although CFDA established the state and provincial technology assessment centres and testing centres, technical resources are inadequate when compared with the US and EU. In addition, for the effectiveness of some products, the FDA requires clinical trials for the devices verification; the EU directives encourage manufacturers to use literature reviews and laboratory documents to verify the effectiveness of the devices; similar to the FDA’s requirements, the CFDA requires clinical trials for some devices verification. Last but not least, as described before, the EU system permits the applicants to choose the Notified Bodies that put their devices though the least stringent reviews and identify the easiest

way to get the CE mark; in this respect the FDA and CFDA are different from the EU system.

The post-market surveillance is an important guarantee for ensuring that the devices continue to be safe and effective. The US and EU's medical devices regulatory legislation have strict requirements for the marketed devices. Manufacturers must establish and follow quality systems to help ensure that their devices consistently meet applicable requirements. The quality system is known as current good manufacturing practices (CGMP's). This quality system, combined with medical device recalls (MDR), medical device tracking and Medical Product Safety Network (MedSun), are beneficial to the public health protection. The EU has the vigilance system for post-market surveillance, such as EUDAMED. China established the adverse event monitoring system, adverse event information networks, medical devices re-evaluation and medical device recalls to protect public health.

<4> *Summary*

Table 5-3 Summary of key elements of the regulatory systems that control the marketing of medical devices in the US, EU and China.

Region/statutory regulator	Low risk	Medium risk	High risk
US	Comply with QS Regulation GMPs excluding design controls.	Comply with full QS Regulation GMPs.	Comply with full QS Regulation GMPs.
FDA	Notify FDA of establishment and device listings.	Submit 510(k) premarket notification; About 10% of 510(k) submissions require clinical data.	Submit premarket approval application—PMA; Market approval on review of extensive safety and effectiveness data.
EU	Manufacturer's self-declaration of conformity to the	Declaration of conformity to the Essential Requirements	Declaration of conformity to the Essential Requirements

	Essential Requirements.	supported by Notified Body certifications.	supported by Notified Body certifications.
Competent Authorities	Manufacturer informs Competent Authority for devices record-filing; CE mark indicates compliance.	Notified Body informs Competent Authority of certificates issued; CE mark with Notified Body number indicates compliance.	Notified Body informs Competent Authority of certificates issued; CE mark with Notified Body number indicates compliance.
China	Comply with GMPs requirements; GB standards or YY standards or CCC mark indicate compliance.	Comply with GMPs requirements; GB standards or YY standards or CCC mark indicate compliance.	Comply with GMPs requirements; GB standards or YY standards or CCC mark indicate compliance.
CFDA	Manufacturer submits application to the city's CFDA for device record-filing; No clinical data required.	Manufacturer submits application to the province's CFDA for device registration; Clinical data required, except exemption devices.	Manufacturer submits application to the central CFDA for device registration; Clinical data required, except exemption devices.

Source: author's compilation and Tobin [192]

5.6 Discussion

This review of medical devices regulation in the US, EU and China illustrates that every regulatory system has its particular advantages and disadvantages. Although the US and EU regulations have shortcomings, they still play a vital role in the global medical devices market. Some studies have shown that some high-risk devices gained an EU CE mark but when they tried to enter the US market they were withdrawn by the US FDA due to the safety risks [134, 135].

In the US and EU, the legislation clearly prescribes that the device manufacturer or applicant will take the main responsibilities for device safety and all the consequences resulting from the device performance. However, the old Chinese legislation did not clearly define this situation, the CFDA bears some responsibility for the medical devices' use, failures, and even adverse events. The new regime clearly delineates every medical

device related participant's responsibilities. For example, medical device manufacturers, distributors and users shall monitor adverse events. If any adverse events are identified, they shall report it to the medical device adverse event monitoring technical institutes [193].

The new regulations are intended to establish a more efficient and scientific regulatory regime for supervision and administration of medical devices. Risk management has been introduced to the new regulations. In addition, the CFDA pays more attention to the Class III devices supervision and moderates the Class I devices oversight. The old regulations required that all the Class II and Class III devices need clinical trials, inspection and approval by the provincial CFDA and central CFDA, respectively [159]. The exemption from clinical trials for some special circumstances has been introduced in the new regulations. Moreover, the registration is replaced by record-filing for Class I devices application, which make the registration process more efficient.

As previously described, due to there not being a national unified product naming and coding system; too many devices are classified as high-risk devices when they should not be categorised at the high-risk level, resulting in an unnecessary waste of effort and low efficiency of medical device supervision in China. Nevertheless, the new regulations have tried to establish a unique unified national medical device naming and coding system, to reduce the incidence of: "the same products having different names or the same names referring to different products" , and the central CFDA will analyse and evaluate medical device's risk, to adjust the "classification catalogue" [194].

Post-market surveillance is an important guarantee to ensure that the devices continue to be safe and effective. The US and EU's medical devices regulatory legislation have strict requirements for the marketed devices. For example, the EU has the vigilance system for post-market surveillance, such as the EUDAMED. The adverse events and recall of medical devices does not appear in the old regulations. The new regulations combined the central CFDA Decree 425 and MOH Decree 82 requirements, they clearly describe the device participants' responsibilities and have established the medical device adverse events monitoring system and information networks to control adverse events and recalls; they have established a re-evaluation system for registered medical devices to regulate supervisory activities.

In addition, the US Congress passed medical device regulations (21 CFR 800-1299), therefore the US medical device regulations have a high legal status. In contrast, the new *Regulations for the Supervision and Administration of Medical Devices* released by the Chinese State Council are administrative regulations, the legal status is not higher than the laws or regulations passed by the National People's Congress (NPC)[23]. The first edition of the *Drug Administration Law of the People's Republic of China* was released by NPC in 1984 and that came into force in 1985. Compared with the Drug Administration Law, the medical device regulations were established late. In 1996, the former State Pharmaceutical Administration issued the *Measures for the Administration of Medical Device Registration*, which adopted the developed countries' registration system. The new medical device regulations are in line with China's national conditions. With the development of the economy, the regulations have continued to be modified and changed to this day.

5.7 Conclusions

This chapter briefly reviews the US, EU and Chinese medical devices regulations and makes a comparison of the relatively mature regulations in the US and EU with those of China; this is useful as it provides guidance for the development and enhancement of the management of the Chinese medical device regulations. Furthermore, it is vital for investors to understand the regulatory environment into which they are entering. Some of the US and EU medical device regulations' philosophy has been adopted by the Chinese authorities, and reflected in the *Regulations for the Supervision and Administration of Medical Devices* (2014). For instance, premarket approval and quality system management.

The overview of the medical device regulations in the US, EU and China demonstrates that they have similar regulations but the EU devices classification system is considered more reasonable. The US and Chinese centralized systems seem to provide some safety benefits, while the EU decentralized system has vulnerabilities, which have been outlined. Each jurisdiction has its own regulatory framework with different legislation [133].

[23] The National People's Congress (NPC) is the national legislature of the People's Republic of China. The NPC is structured as a unicameral legislature.

The changes made in the new regulations demonstrate the Chinese government's efforts to upgrade and maintain an effective regulatory framework for the medical device market. The Chinese government has promulgated the new regulations, which covers various perspectives of the regulatory regime of medical devices, such as device classification and registration, supervision of production and distribution, etc. Driven by the more powerful regulatory requirements under the new regulations, the Chinese medical device market will become increasingly dynamic in the future.

Further in-depth research on this topic will be carried out in the future. Some regulations and policies still need modification and the recommendation is for more studies to understand the changing market environments, this should result in continuous improvement of policies.

Chapter 6 The Chinese Medical Device Market Investment Guidance

6.1 Introduction

The medical device market is one of the most attractive and profitable areas in the global economy. Since China opened its doors to the world, it has attracted increasing amounts of foreign investment. The Chinese medical device market is currently one of the most promising and fastest growing markets, which is the second largest market in the world with 200 billion yuan total sales in 2013. According to Chapter 4 analysis, the global medical device market is highly centralized, the market share of the developed countries accounted for more than 80% of the global medical device market share (US: 42.4%, Europe: 33%, Japan: 11%) in 2011. Medical devices are a growth industry in China due to increasing medical expenditure, rising healthcare consumption and health awareness improvements. By studying the distribution of the Chinese medical device market and regional advantages, investment strategies for investors who are doing business in China can be optimised and enhanced.

6.2 Data

Data on the medical device industry total output value of each province in China from 2001 to 2011 were collected from the China Statistics Yearbook on High Technology Industry [195], the detailed data are shown in Appendix 7. Other data such as gross regional product and gross domestic product of China are collected from the National Bureau of Statistics of the People's Republic of China [196] (see Appendix 9 and Appendix 10). According to Appendix 7, most of these provinces' medical device output value has grown steadily from 2001 to 2011, which demonstrates an increase in the expansion of the Chinese medical device industry. The average of the Chinese medical device industry total output value was calculated based on the information in Appendix 7, detailed data shown in Appendix 8 (listed in declining trend). Data show Jiangsu, Zhejiang, Guangdong, Shandong, Shanghai and Beijing are the most productive provinces in China[24]. Each Chinese province was classified into five levels according to

[24] The administrative divisions of China include: 23 provinces (including Taiwan), 5 autonomous regions (Guangxi, Ningxia, Xinjiang, Inner Mongolia and Tibet), 4 Municipalities (Beijing, Tianjin, Shanghai and Chongqing) and 2 special administrative regions (Hong Kong and Macau).

its average total output value of the medical device industry, which are ≤ 1,000, 1,000-4,000, 4,000-7,000, 7,000-10,000 and ≥ 10,000. This information is plotted on the map of China (see Figure 6-1). In this study, we select 30 provinces (including 4 autonomous regions and 4 municipalities), the data on the medical device industry total output value, do not include: Tibet, Taiwan, Hong Kong and Macau.

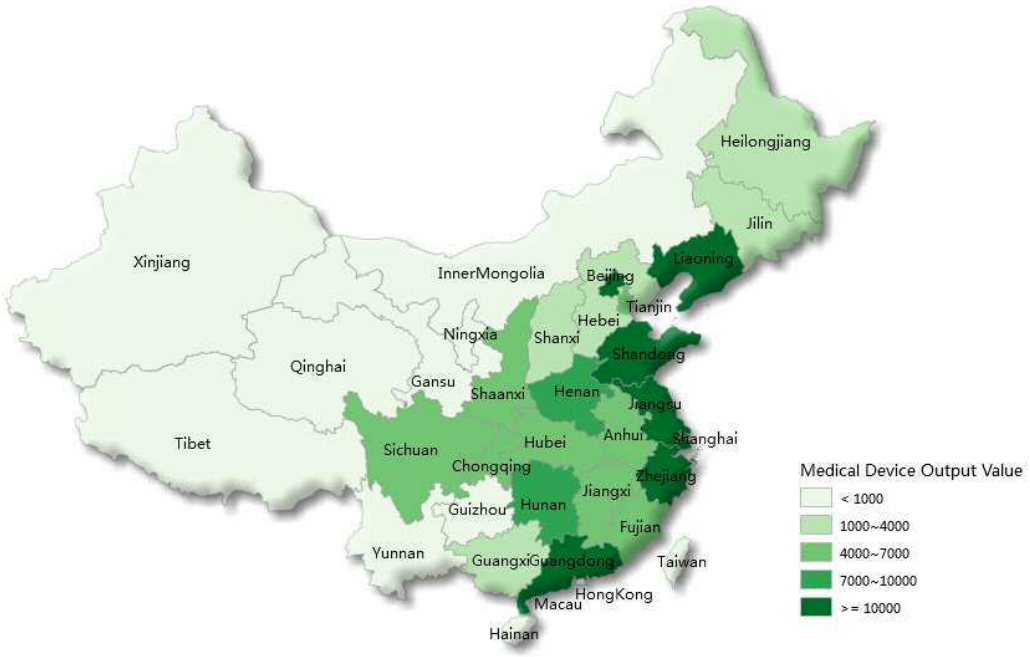

Figure 6-1 Geographic distribution of the Chinese medical device industry.

6.3 Methods

A location quotient (LQ) has been used as a proxy for the spatial or geographic dependency of a given economic sector [197, 198]. LQ is the ratio of an industry's share of the economic activity of the regional economy being considered to that industry's share of the national economy [199]. The basic formula for the location quotient in regional economic sector can be described as: [200]

$$LQ_{ij} = \frac{E_{ij} / E_i}{\sum_i E_{ij} / \sum_i E_i} \qquad (6\text{-}1)$$

Where: E_{ij}=Regional i employment in industry j

E_i=Total regional i employment

$\sum_i E_{ij}$ =National employment in industry j

$\sum_i E_i$ =Total national employment

The LQ analysis technique is frequently calculated on the basis of employment, but employment can be defined in many ways such as service or manufacturing [201]. Industry LQ is a way of quantifying how "concentrated" an industry is in a region compared to a larger geographic area, such as the state or nation [202]. Therefore, variables in equation (6-1) could be defined as follows: E_{ij}= economic activity in area i industry j; E_i= total economic activity in area i; $\sum_i E_{ij}$ = economic activity of industry j in the whole area and $\sum_i E_i$ = total economic activity in the whole area. In this chapter, the locational analysis technique is applied to the following variables: E_{ij}= provincial output value of medical device industry j in area i; E_i= provincial gross regional product; $\sum_i E_{ij}$ = China output value of medical device industry j and $\sum_i E_i$ = China gross domestic product.

If LQ is greater than 1, it is assumed that medical device industry output value exceeds the local demand and appears to be exporting much of its goods to non-local markets or areas, which means the medical device industry in this region has comparative advantages. If LQ is equal to or less than 1, it indicates that the medical device industry does not export from the region, and the output value of the medical device industry does not meet the local demand. Hence, industry in the region is not strongly competitive [199, 203].

LQ is an index that measures regional industrial professional level (specialization) and concentration (see Table 6-1). The higher the LQ, the higher the industrial concentration in the region. LQ is a ratio, which reflects the relative degree of professional level skills in one region rather than the actual degree of specialization in this region. For instance, if the medical device industry has high LQ in one region, this result may be because this region has a high output value in the medical device industry or this region has low

regional product output value but has high medical device output value. Therefore, we introduce "market share (MS)[25]" into this study. Detailed data were shown in Table 6-2. If LQ > 1 and MS is higher than the country average level (in the study, average level=100%÷30=3.33%), the industry in the region has comparative advantages. The matrix illustrates the relationship between LQ and MS (Figure 6-2).

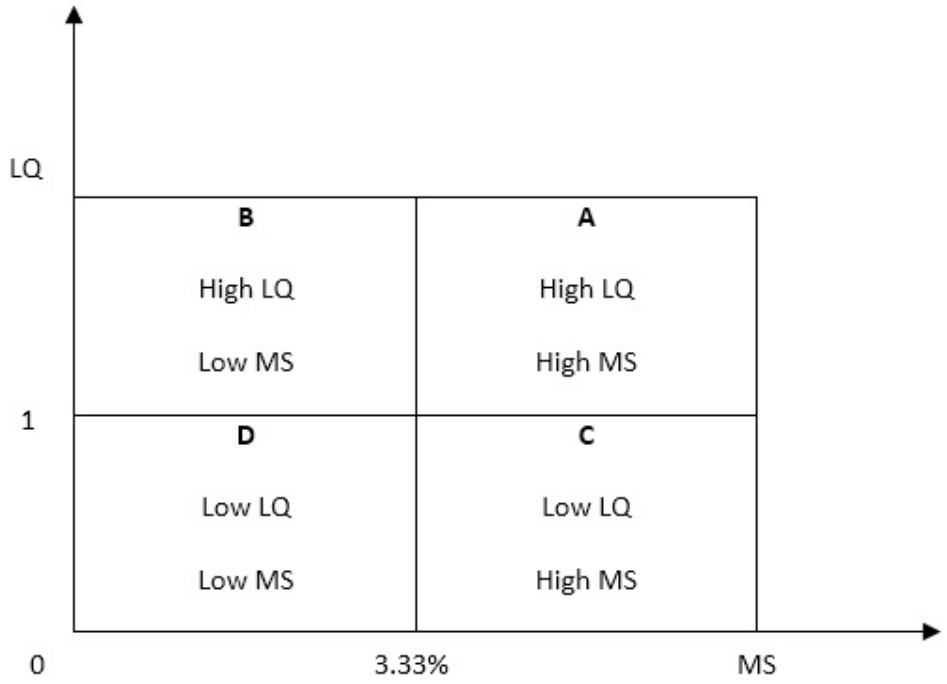

Figure 6-2 Matrix of each province's industry professional level.

Area A has a high LQ and high MS; provinces in this area have a high professional industrial level and have comparative advantages throughout the country. Area B shows that the region's total industrial scale is too small; industrial output value has a significant share of the regional commercial activity, but actually the industrial level does not have comparative advantages. Area C illustrates that the industry has comparative advantages in the country, but other industries in this region also have a high level and comparative advantages, so this industry has a low LQ in the region. Area D means that industry does not have any comparative advantages in the region or the whole country.

[25] In this study, market share= $E_{ij} / \sum_{i} E_{ij}$ (6-2)

6.4 Results

Based on the data (shown in Appendix 7, Appendix 9 and Appendix 10), using the formula for the LQ (equation (6-1)), the LQ results are evaluated for each province, see Table 6-1.

Table 6-1 LQ of each province in China from 2001 to 2011.

LQ	Beijing	Tianjin	Hebei	Shanxi	Inner Mongolia	Liaoning	Jilin	Heilong-jiang
2001	3.569	1.730	0.292	0.190	0.024	0.891	0.398	0.397
2002	3.173	1.475	0.246	0.149	0.020	0.930	0.348	0.255
2003	3.136	1.542	0.307	0.217	---	0.914	0.435	0.158
2004	2.586	1.165	0.251	0.179	0.004	0.809	0.498	0.213
2005	2.477	0.894	0.238	0.251	---	0.728	0.295	0.192
2006	2.286	0.858	0.230	0.217	---	0.718	0.255	0.181
2007	1.986	0.659	0.252	0.201	---	0.832	0.257	0.226
2008	1.792	0.751	0.227	0.136	0.004	0.931	0.390	0.173
2009	1.631	0.645	0.283	0.146	0.022	0.954	0.403	0.176
2010	1.412	0.607	0.288	0.142	0.029	0.857	0.452	0.153
2011	1.247	0.417	0.264	0.138	0.016	0.693	0.415	0.114
	Shang-hai	Jiangsu	Zhejiang	Anhui	Fujian	Jiangxi	Shandong	Henan
2001	3.015	2.099	2.399	0.333	0.506	0.350	0.640	0.275
2002	2.840	1.848	2.044	0.534	0.604	0.635	0.612	0.257
2003	2.304	1.709	2.198	0.573	0.738	0.511	0.633	0.221
2004	2.435	1.572	1.682	0.486	0.560	0.596	0.653	0.439
2005	2.026	1.577	2.023	0.478	0.480	0.497	0.824	0.349
2006	2.032	1.752	2.041	0.454	0.476	0.553	0.952	0.531
2007	1.925	1.935	2.032	0.504	0.465	0.663	0.967	0.595
2008	1.838	2.683	1.598	0.283	0.390	0.747	0.832	0.619
2009	1.526	2.798	1.683	0.611	0.396	0.763	0.897	0.679
2010	1.542	2.948	1.698	0.640	0.383	0.797	0.821	0.607
2011	1.377	3.389	1.427	0.654	0.389	0.788	0.834	0.710

	Hubei	Hunan	Guang-dong	Guangxi	Hainan	Chong-qing	Sichuan	Guizhou
2001	0.869	0.592	0.796	0.131	0.185	2.194	0.310	0.150
2002	0.830	0.616	0.819	0.171	0.133	2.017	0.362	0.184
2003	0.632	0.347	0.878	0.236	0.039	2.152	0.390	0.258
2004	0.430	0.329	1.479	0.193	0.015	1.691	0.327	0.258
2005	0.647	0.390	1.433	0.195	0.003	1.467	0.343	0.210
2006	0.595	0.363	1.212	0.165	---	1.339	0.411	0.188
2007	0.528	0.381	1.295	0.186	---	1.118	0.446	0.197
2008	0.423	0.865	1.079	0.206	---	1.080	0.632	0.117
2009	0.377	0.780	0.842	0.230	---	0.949	0.693	0.158
2010	0.314	0.911	0.841	0.261	---	1.126	0.336	0.113
2011	0.252	1.026	0.788	0.213	0.229	0.866	0.353	0.089
	Yunnan	Shaanxi	Gansu	Qinghai	Ningxia	Xinjiang		
2001	0.390	1.411	0.241	---	1.936	0.014		
2002	0.405	1.291	0.247	---	1.980	0.007		
2003	0.331	1.087	0.362	0.222	1.472	0.021		
2004	0.231	1.278	0.178	0.233	1.256	0.027		
2005	0.190	0.855	0.138	0.191	0.938	0.033		
2006	0.212	0.978	0.090	0.121	0.214	0.025		
2007	0.181	0.796	0.081	0.137	0.572	0.027		
2008	0.180	0.427	0.030	0.136	0.487	0.018		
2009	0.160	0.749	0.066	0.065	0.496	0.023		
2010	0.147	0.595	0.050	0.053	0.406	0.020		
2011	0.092	0.631	0.033	0.053	0.327	0.010		

LQ is a relative result, which cannot reflect the real industrial professional level, in this study, two indicators (LQ and MS) have been selected to measure the industrial professional level. The MS (equation (6-2)) for each province was evaluated from 2001 to 2011, which shown in Table 6-2.

Table 6-2 MS of each province in China from 2001 to 2011.

	Beijing	Tianjin	Hebei	Shanxi	Inner Mongolia	Liaoning	Jilin	Heilong-jiang

2001	9.26%	2.90%	1.49%	0.31%	0.03%	4.09%	0.74%	1.29%
2002	11.42%	2.64%	1.23%	0.29%	0.03%	4.22%	0.68%	0.77%
2003	11.60%	2.93%	1.57%	0.46%	---	4.04%	0.85%	0.47%
2004	9.80%	2.27%	1.33%	0.40%	0.01%	3.38%	0.97%	0.63%
2005	9.22%	1.79%	1.30%	0.57%	---	3.10%	0.58%	0.57%
2006	8.32%	1.73%	1.24%	0.48%	---	3.07%	0.50%	0.52%
2007	7.36%	1.30%	1.29%	0.45%	---	3.49%	0.51%	0.60%
2008	6.34%	1.61%	1.16%	0.32%	0.01%	4.05%	0.80%	0.46%
2009	5.82%	1.42%	1.43%	0.32%	0.06%	4.26%	0.86%	0.44%
2010	4.96%	1.39%	1.47%	0.33%	0.09%	3.94%	0.98%	0.40%
2011	4.29%	1.00%	1.37%	0.33%	0.05%	3.26%	0.93%	0.30%

	Shanghai	Jiangsu	Zhejiang	Anhui	Fujian	Jiangxi	Shandong	Henan
2001	13.61%	18.21%	14.76%	1.00%	1.96%	0.69%	5.51%	1.42%
2002	13.55%	16.29%	13.59%	1.56%	2.24%	1.29%	5.23%	1.29%
2003	11.36%	15.66%	15.71%	1.65%	2.71%	1.06%	5.63%	1.12%
2004	12.29%	14.75%	12.26%	1.45%	2.02%	1.29%	6.14%	2.35%
2005	10.04%	15.61%	14.70%	1.39%	1.70%	1.09%	8.25%	2.00%
2006	9.74%	17.53%	14.85%	1.29%	1.68%	1.19%	9.72%	3.07%
2007	9.05%	18.94%	14.34%	1.40%	1.62%	1.45%	9.38%	3.36%
2008	8.23%	26.47%	10.92%	0.80%	1.34%	1.66%	8.20%	3.55%
2009	6.74%	28.28%	11.35%	1.80%	1.42%	1.71%	8.91%	3.88%
2010	6.59%	30.41%	11.73%	1.97%	1.41%	1.88%	8.01%	3.49%
2011	5.59%	35.19%	9.76%	2.12%	1.44%	1.95%	8.00%	4.04%

	Hubei	Hunan	Guang-dong	Guangxi	Hainan	Chong-qing	Sichuan	Guizhou
2001	3.70%	2.15%	7.73%	0.27%	0.09%	3.50%	1.25%	0.15%
2002	2.91%	2.12%	9.18%	0.36%	0.07%	3.34%	1.42%	0.19%
2003	2.21%	1.19%	10.24%	0.49%	0.02%	3.60%	1.53%	0.27%
2004	1.51%	1.16%	17.45%	0.41%	0.01%	2.85%	1.30%	0.27%
2005	2.28%	1.37%	17.33%	0.43%	0.00%	2.43%	1.37%	0.23%
2006	2.08%	1.27%	14.68%	0.37%	---	2.16%	1.64%	0.20%
2007	1.86%	1.35%	15.48%	0.41%	---	1.97%	1.77%	0.21%
2008	1.53%	3.18%	12.64%	0.46%	---	1.99%	2.54%	0.13%
2009	1.43%	2.99%	9.76%	0.52%	---	1.82%	2.88%	0.18%

2010	1.25%	3.64%	9.64%	0.62%	---	2.22%	1.44%	0.13%
2011	1.05%	4.27%	8.87%	0.53%	0.12%	1.83%	1.57%	0.11%

	Yunnan	Shaanxi	Gansu	Qinghai	Ningxia	Xinjiang
2001	0.74%	2.37%	0.24%	---	0.53%	0.02%
2002	0.78%	2.42%	0.25%	---	0.62%	0.01%
2003	0.62%	2.07%	0.37%	0.06%	0.48%	0.03%
2004	0.44%	2.54%	0.19%	0.07%	0.42%	0.04%
2005	0.36%	1.74%	0.14%	0.06%	0.31%	0.05%
2006	0.39%	2.04%	0.09%	0.04%	0.07%	0.04%
2007	0.32%	1.72%	0.08%	0.04%	0.20%	0.04%
2008	0.33%	0.99%	0.03%	0.04%	0.19%	0.02%
2009	0.29%	1.79%	0.07%	0.02%	0.20%	0.03%
2010	0.27%	1.50%	0.05%	0.02%	0.17%	0.03%
2011	0.17%	1.67%	0.03%	0.02%	0.15%	0.01%

Based on the data in Table 6-1 and Table 6-2, we used the criteria defined in Figure 6-2 to evaluate the industrial professional level of each province, which is shown in Table 6-3.

Table 6-3 Industry professional level of each province in China from 2001 to 2011.

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Beijing	A	A	A	A	A	A	A	A	A	A	A
Tianjin	B	B	B	B	D	D	D	D	D	D	D
Hebei	D	D	D	D	D	D	D	D	D	D	D
Shanxi	D	D	D	D	D	D	D	D	D	D	D
Inner Mongolia	D	D	…	D	…	…	…	D	D	D	D
Liaoning	C	C	C	C	D	D	C	C	C	C	D
Jilin	D	D	D	D	D	D	D	D	D	D	D
Heilongjiang	D	D	D	D	D	D	D	D	D	D	D
Shanghai	A	A	A	A	A	A	A	A	A	A	A
Jiangsu	A	A	A	A	A	A	A	A	A	A	A
Zhejiang	A	A	A	A	A	A	A	A	A	A	A
Anhui	D	D	D	D	D	D	D	D	D	D	D
Fujian	D	D	D	D	D	D	D	D	D	D	D
Jiangxi	D	D	D	D	D	D	D	D	D	D	D

Shandong	C	C	C	C	C	C	C	C	C	C	C
Henan	D	D	D	D	D	D	C	C	C	C	C
Hubei	C	D	D	D	D	D	D	D	D	D	D
Hunan	D	D	D	D	D	D	D	D	D	C	A
Guangdong	C	C	C	A	A	A	A	A	C	C	C
Guangxi	D	D	D	D	D	D	D	D	D	D	D
Hainan	D	D	D	D	D	…	…	…	…	…	D
Chongqing	A	A	A	B	B	B	B	B	D	B	D
Sichuan	D	D	D	D	D	D	D	D	D	D	D
Guizhou	D	D	D	D	D	D	D	D	D	D	D
Yunnan	D	D	D	D	D	D	D	D	D	D	D
Shaanxi	B	B	B	B	D	D	D	D	D	D	D
Gansu	D	D	D	D	D	D	D	D	D	D	D
Qinghai	…	…	D	D	D	D	D	D	D	D	D
Ningxia	B	B	B	B	D	D	D	D	D	D	D
Xinjiang	D	D	D	D	D	D	D	D	D	D	D

A=high LQ, high MS; B=high LQ, low MS; C=low LQ, high MS; D=low LQ, low MS.

Area A (high LQ, high MS): From 2001 to 2011, there are four administrative divisions that stay in this area. They are two municipalities (Beijing and Shanghai) and two provinces (Jiangsu and Zhejiang). These four regions have the top medical device industrial professional level and competitive advantages over the rest of the country. Moreover, they accounted for about 55% of the medical device output market share in 2011 according to Table 6-2.

Area B (high LQ, low MS): There are four regions that stayed in area B. From 2005 to 2011, the industrial professional level of Tianjin, Shaanxi and Ningxia moved to area D. Chongqing stayed in area A from 2001 to 2003 but dropped back to area B from 2004 to 2008. These four regions are basically well developed with a good industrial professional level but their MS has not reached the country's average level; they thus do not have a competitive advantage. However, compared to other industries in these four regions, the medical device industry has some competitive advantages in the local area, so the medical device industry in these four regions has the capacity to develop.

Area C (low LQ, high MS): Shandong province has been in this area for 11 years. Liaoning also occupies this area except for 2005, 2006 and 2011. Henan was in area D from 2001 to 2006; from 2007, Henan moved to area C. Provinces in area C have a national competitive advantage in their medical device industry, but low LQ means that the medical device industry does not have competitive advantage in their provinces. However, some strong industries exist in their provinces.

Area D (low LQ, low MS): more than half the provinces (17) stayed in area D from 2001 to 2011. The development of the medical device industry in these provinces was slow. The professional level of the medical device industry in these provinces does not have a competitive advantage and the industry output value was also lower than the country average level.

Area C→A: Guangdong, as China's major economic province, plays a significant role in the Chinese economy. Its medical device industrial professional level moved from area C to area A, which means Guangdong's medical device industry is leading the country. Based on the data, the medical device industry is on a rising trend, with a growing contribution to Guangdong's industrial output. From Table 6-2 we can see Guangdong accounts for about 12% of medical device output value market share in China.

6.5 Discussion

Using the geographic distribution of the Chinese medical device industry (Figure 6-1) together with the LQ and MS results indicates that the Chinese medical device industry is mainly concentrated in Bohai Economic Rim (Beijing, Shandong, Liaoning, etc.) in the North, and the Southeastern zone, which are two well-developed economic zones: Yangtze River Delta (Shanghai; Jiangsu and Zhejiang) in the East and Pearl River Delta[26] (Guangdong) in the South. These economic zones and cities are located in the industry professional level matrix area A and area C. Medical device industries concentrated in these areas have a competitive advantage; they took about 77% market share in 2011. Beijing belongs to the Bohai Economic Rim[27]. Despite with the low competitive

[26] Pearl River Delta Economic Zone including Guangdong Province; Hong Kong and Macau.
[27] The Bohai Economic Rim has traditionally been involved in heavy industries and manufacturing, which including Beijing; Tianjin; Hebei; Liaoning and Shandong which surrounds the Bohai Sea.

advantage in the local regions (low LQ), Liaoning and Shandong have high market share (area C) and high average output value in the medical device industry according to Appendix 8, which constitutes the leading regional medical device industry in China, the development trend will similar to Guangdong's. Except Chongqing, the majority of provinces are located in matrix area B and area D, which do not have competitive advantages and have a small medical device industry output value.

The LQ of Beijing; Shanghai; Jiangsu and Zhejiang is not high, and shows a decreasing or fluctuating trend from 2001 to 2011. The medical device industrial professional level does not have a comparative advantage compared to other high-tech industries. Moreover, for one industry, the standard deviation of LQ (SDLQ) between regions indicates the difference in industrial professional level, which means the higher the SDLQ, the more concentrated and the higher professional level industrial region [203]. The SDLQ of the medical device industry was 0.96 in 2001. Compared with the SDLQ of other high-tech industries such as the pharmaceutical industry (1.22); aircraft and spacecraft (2.13) and electronic and telecommunication equipment industry (2.09) in 2001 [203], the medical device industry has a low concentration level, which means the medical device industry in China is fragmented, and only concentrated in particular regions such as the three economic zones.

Potential investors are interested to know, which regions are best for investment in the Chinese medical device market. Based on the analysis above, three economic zones (Yangtze River Delta; Pearl River Delta and Bohai Economic Rim) have always enjoyed prosperous development of the medical device industry in China. The population of the three economic zones accounts for 25% of the total Chinese population; accounting for approximately 40% of GDP; foreign businesses account for 70% of investments and control 77% of total import and export value [204]; medical device industry output value and sales account for 75% of the total output value and sales.

The three economic zones have something in common. (1) A strong industrial base to support medical device development, electronics and mechanical equipment manufacturing contributing to technical cooperation and product support; (2) Developed transportation systems are conducive to trade and technical exchanges domestically and internationally; (3) The most prestigious Chinese universities, colleges and education

institutions located in these areas, they provide potential human resources and knowledge-based professionals; (4) Strong medical research and clinical level due to a large number of hospitals being located in these areas; and (5) Strong financing channels including domestic and international capital. The three economic zones also have their own characteristics. Yangtze River Delta and Bohai Economic Rim are multi-province large areas, which historically have a good medical device manufacturing track record. The development of manufacturing and chemical industries has made these two areas leaders in the medical device industry. The Pearl River Delta Economic Zone is part of Guangdong Province, which previously had poor medical device manufacturing. However, the rapid speed of development of the medical device industry in this area has benefited from China's opening-up policy and introduced foreign capital, which has caused the medical device industry and electrical manufacturing to catch up. Moreover, Guangdong Province used the advantages of the opening-up policy to cooperate with Hong Kong and Macau, this has turned the Pearl River Delta into an internationally competitive area. Detailed information will be described in Chapter 7.

Jiangsu, Zhejiang, Guangdong, Shandong, Shanghai, Beijing and Liaoning were in the top 7 of the average total medical device industry by output value from 2001 to 2011. Furthermore, the sales profits of these seven regions are 13,770; 5,730; 5,880; 4,160; 4,600; 4,330 and 2,200 million yuan per annum respectively, which accounted for 74.87% of total medical device profits (54,320 million yuan) in 2010 [195]. Therefore, the three economic zones have comparative advantages due to their industrial scale and profits. These results are inseparable from the government's financial and support policy. In order to facilitate the continued development of high-tech industry, the Chinese central and local governments established the China National High-Tech Industrial Development Zone, which contains many areas of activity, such as: electronics and information technology; bioengineering and medical imaging; aerospace technology; nuclear application technology and energy-efficient technologies. By the end of 2014, there were 114 National High-Tech Industrial Development Zones in China, with 23 of the high-tech industrial zones located in the Bohai Economic Rim; Yangtze River Delta and Pearl River Delta Economic Zone have 18 and 9, respectively [205]. The rapid economic growth and huge market potential of the Chinese medical device market is recognised by many international companies such as GE, Philips and Siemens, who have been expanding their business in China in recent years. For example, GE Medical Industrial Park (Beijing) is

one of the largest R&D bases in the world; Philips Healthcare established medical imaging bases in Suzhou (Jiangsu Province) [206]; Siemens Healthcare has two wholly owned subsidiaries in Shanghai and Shenzhen (Guangdong Province) [207].

This study has its limitations. The size of the sample is too small to perform statistical analysis. And, the data collected only run up to 2011. Moreover, the disadvantage of the LQ method is that it may not reflect the actual degree of specialization. For instance, Guangdong has a low LQ but is a promising market, while Ningxia has a high LQ but seems to be an underdeveloped region. The LQ method is not the only way to assess the industrial professional level but is probably the most frequently employed. Some methods like net present value (NPV) and real option [208] can also assess the market. But by combining the LQ and MS methods, the LQ's error is reduced, making the findings of this study more reliable. Despite these limitations, the findings of this study provides some guidance for investors who want to do business in the Chinese medical device market.

6.6 Conclusion

The Chinese medical device market, like China's economy, is developing rapidly. It is clear that the medical device market in China has great investment potential. It is considered a promising market area in which companies, especially foreign companies, are already making investments. Moreover, the Chinese government's healthcare reforms, rising income and availability of insurance; improving medical infrastructure create a better investment environment. Furthermore, the new Chinese medical device regulations that came into force in 2014, made the Chinese medical device market more organised, which is beneficial for investors.

This chapter illustrates the geographical distribution of the Chinese medical device industry, combined with the LQ assessment, to reveal the medical device industry's professional level and degree of concentration in each province, providing guidance for investors who are interested in medical device investment in China. The LQ and MS matrix reveals that the best investment regions in China are: Bohai Economic Rim, Yangtze River Delta and Pearl River Delta Economic Zones. The Chinese government has awarded favourable policy preferences to these regions in order to attract more

investment, hence, the investment environment has been relatively advantageous over other regions in China. Therefore, the three economic zones were chosen as the priority regions for the investors who want to invest in the Chinese medical device market.

Chapter 7 The Chinese Medical Device Market Competitive Analysis

The Chinese medical device market does not have a strong competitive advantage compared with the US and EU market. However, there is no doubt that the Chinese medical device market is currently one of the most promising and fastest growing markets. This chapter will analyse the competitiveness of the market.

7.1 The Chinese medical device market SWOT analysis

The strengths, weaknesses, opportunities and threats (SWOT) analysis is an integrated tool to identify the internal and external factors that characterise the strategic position of the market [209].

Table 7-1 The SWOT matrix of the Chinese medical device market.

	Helpful to achieve the objective	Harmful to achieve the objective
Internal Origin product and company attributes	Strengths (S)	Weaknesses (W)
	1, Has more low-end technology products, which have low-cost advantages compared with foreign companies' products 2, With the rapid development, domestic companies have some technical strengths and research foundation 3, Academic institutions	1, Less R&D funding 2, Less technical patents 3, Low-level repetitive production and low quality products 4, High-tech supporting technical level weaker than the developed countries

	Opportunities (O)	Threats (T)
External Origin environment and market attributes	1, Huge market demand, growing and aging population 2, The Chinese government's policies to promote the market development 3, The quality and standards tend to be consistent with the international standards 4, The new medical device regulations improve the supervision and management 5, Scientific progress	1, Globalization 2, The influx of foreign funds

Source: author's compilation and Shang [210] and Fang [211]

Table 7-1 summarizes the SWOT of the Chinese medical device market. The competition of the low-end medical device market is fierce and the high-end medical device market is dominated by a few foreign companies. According to previous chapters' analysis, China has a huge population especially the aging population, number of hospital visits, the number of hospitals and diseases, all these driving forces indicate that the market still has room to improve.

Strengths:

The Chinese medical device companies have a very small living space in the high-end medical device market, thus, they have focused on the middle and low-end of the market. In the middle and low-end medical device market, the Chinese products have competitive advantages on price compared with foreign companies. Moreover, the Chinese companies have the technology of low-end medical devices production, which are able to produce high quality products. More and more universities and academic institutions established medical device research centres and relevant courses, the number of medical professionals has increased in recent years.

Weaknesses:

The Chinese medical device companies have less R&D funding, this is also the important weakness of the Chinese medical device market. This results in less technical patents, low-level repetitive production and some low quality products. The Chinese middle and low-end medical device market is dominated by domestic companies, the majority of

which generally lack the expertise and experience compared to Western standards. There are only a few Chinese medical device companies are producing high-end medical devices and products.

Opportunities:

The Chinese medical device market is one of the fastest growing markets in the world. Huge market demand is driven by the growth of the aging population and improved life quality (rising incomes). Due to the changing diets and air pollution, the incidence of cancer and other chronic diseases keeps rising, this has made people willing to pay more on their health and created opportunities for pharmaceutical, medical device and hospital management that provides a wide range of healthcare products and services. Moreover, the Chinese central government invested in medical infrastructure in rural areas, updated many medical devices, which promote the medical device industry development. In addition, the new medical device regulations came into force in 2014, this strengthens the market supervision and management, resulting in many Chinese products that are encouraged to have high quality and are consistent with the international standards. The scientific progress will bring the latest medical devices to the market. Last but not least, the development of the market need funds, therefore the market becomes one of the most popular industries which can attract venture capital investment.

Threats:

After joining the World Trade Organization (WTO) and tariff reductions, more foreign products have entered into the Chinese market. The influx of foreign funds and products has increased, medical device market face fierce competition. The high-end medical device market is dominated by the foreign companies, while foreign companies have begun to get involved in the middle and low-end medical device market. Foreign companies rely on their technical superiority and brand effect, to further exploit and occupy the Chinese medical device market. Foreign companies began to produce cost-effective middle and low-end medical devices, which are acceptable and affordable for the Tier-2 and Tier-1 hospitals and other grass-roots healthcare institutions. Therefore, the Chinese medical device companies are faced with serious threats, even to be acquired by foreign companies, their living space has been compressed. The Chinese medical device companies' products should not only have price advantages, but also have high quality.

7.2 The Chinese medical device market regional competitiveness analysis

In Chapter 6, the LQ and MS methods reveals that the best investment regions for medical devices in China are Bohai Economic Rim, Yangtze River Delta and Pearl River Delta Economic Zones.

7.2.1 Bohai Economic Rim

The Bohai Economic Rim includes two municipalities (Beijing and Tianjin) and three provinces (Liaoning, Hebei and Shandong). The total population has reached 230 million, which accounts for about 17% of the Chinese population, gross regional product reached 11,966,352 million yuan, which accounts for about 25.3% of GDP in 2011. The Bohai Economic Rim has a geographical advantage, as it is located in the centre of Northeast Asia[28]. This unique geographical advantages provide a favourable environment and conditions for the investors and foreign economic cooperation with many areas. The Bohai Economic Rim is the largest industrial-intensive area in China, it is the base of heavy industries and chemical industries, which has competitive advantages in resources and R&D. Moreover, the most prestigious universities, colleges and research institutes are located in this area, which provides scientific and technological human talent. The medical device industry, Chinese medicine and pharmaceuticals together constitute the bioengineering and new medical industries in this area.

7.2.2 Yangtze River Delta

The Yangtze River Delta includes one municipality (Shanghai) and two provinces (Jiangsu and Zhejiang). Total population reached 156 million, it accounts for about 17% of the Chinese population, gross regional product reached 10,062,481 million yuan, which accounts for about 21.3% of GDP in 2011. The Yangtze River Delta is not only the largest, fastest-growing economic area, but also the most promising economic area in China. This region has a strong industrial base, developed economy and convenient transportation, it is China's largest export base.

[28] Northeast Asia includes China, Japan, Korean Peninsula (Democratic People's Republic of Korea (DPRK) and Republic of Korea) Mongolia and the Russian Far East and Siberia.

As the regional leader, Shanghai plays an important roles in the medical device industry. Many medical device companies are located in Shanghai, because Shanghai is an attractive place for foreign investment and human talent. Zhangjiang Hi-Tech Park is one of China's first state-level high-tech zones, which includes the field of software, bio-pharmaceutical and medical devices.

7.2.3 Pearl River Delta Economic Zones

The Pearl River Delta Economic Zones includes one province (Guangdong) and two special administrative regions (Hong Kong and Macau). The development of the Pearl River Delta Economic Zones is primarily thanks to Hong Kong, where it has been a major source of the investments. Total population (Guangdong province) reached 104 million, which accounts for about 8% of the Chinese population, gross regional product reached 5,321,028 million yuan, accounting for about 11.3% of GDP in 2011. The Pearl River Delta Economic Zones is China's third-largest economic zone, the total economic output is only behind Yangtze River Delta and Bohai Economic Rim.

The development of manufacturing industry and medical device industry in Guangdong is mature and very influential in China. Many high-tech companies are located in Shenzhen, which has become China's high-end medical device manufacturing base. The products cover almost all areas of clinical medicine, mainly concentrated in the high-end medical diagnostic imaging devices (such as CT, MRI and ultrasound), radiation therapy products (such as Gamma Knife), medical electronic products (such as various types of patient monitors) and interventional treatment products (such as catheters).

7.2.4 The foreign medical device companies' business activities

Many famous foreign medical device companies are now doing business in China through mergers and acquisitions or joint ventures. In this part we only discuss the main medical imaging companies.

GE Healthcare [212] started doing business in China since 1979, and established the first agency in China in 1986. Currently, GE Healthcare has established more business entities, including wholly owned and joint venture companies. For example, GE Healthcare is to

form a joint venture with Shinva Medical Instrument in Zibo (Shandong Province), which was the first Chinese medical device company (established in 1943). GE Medical Industrial Park (Beijing) is one of the largest R&D bases in the world. The partnership aims to be active in R&D and manufacturing/sales; the production of medical devices includes: CT, MRI and X-rays. GE Healthcare established a factory for ultrasound equipment and patient monitors production in Wuxi (Jiangsu Province). In addition, the production base of MRI in Tianjin is under construction.

The market share of GE Healthcare has reached 50%-60% in the Chinese high-end medical device market, the medical devices are manufactured (especially CT) in China, not only to supply to the local market, but also to provide the worldwide demand. GE Healthcare China exports 70% of its devices but wants to increase its local sales. The revenues from GE Healthcare was one billion US dollars in China in 2008 with increasing sales performance.

Siemens Healthcare [207] has two wholly owned subsidiaries in China, one called Siemens Shanghai Medical Equipment Ltd. (founded in 1992) in Shanghai, which is a R&D base and manufactures CT and X-ray systems; Siemens Healthcare and Shenzhen Mindit Instruments Co. Ltd. established a joint venture in the area of MRI, so the other one is Siemens Mindit Magnetic Resonance Ltd. (founded in 2002) in Shenzhen (Guangdong Province). The market share of Siemens Healthcare is second only to GE Healthcare in China.

Compared with GE Healthcare and Siemens Healthcare, Philips Healthcare's business activities in China were relatively late. In 2004, Philips Healthcare [206] set up a joint venture with Neusoft (Philips holding 51% of company share and Neusoft holding 49%) in Shenyang (Liaoning Province) for developing and manufacturing medical imaging systems (CT, MRI, ultrasound and X-rays) for the Chinese and international markets. Philips Healthcare acquired the Chinese patient monitoring company Shenzhen Goldway Industrial, Inc. in Shenzhen (Guangdong Province) in 2008. Philips Healthcare is the market leader in the global patient monitoring market, which was estimated to be worth approximately USD 3 billion [213]. Philips Healthcare established medical imaging bases for manufacturing CT, MRI and X-rays in Suzhou (Jiangsu Province) in 2009 and purchased Shanghai Apex Electronics in 2010 for ultrasound production.

The Hitachi Medical Corporation [214] established three Medical Systems Corporations in Suzhou (Jiangsu Province), Beijing and Guangzhou (Guangdong Province). In 2002, Hitachi set up a wholly owned subsidiary in Suzhou for manufacturing X-rays for smaller hospitals in China. Moreover, Hitachi invested more to this company to produce lower priced diagnostic imaging devices in 2009. In order to adapt and meet the rising market demand, Hitachi set up a new company in Beijing for developing medical imaging devices in 2006. In the same year, Hitachi set up a wholly owned subsidiary in Guangzhou for manufacturing ultrasound. Aloka, a Japanese manufacturer, is the first company, which transferred its ultrasound manufacturing operations to China in 1996. Since Hitachi acquired Aloka in 2011, Hitachi Aloka's ultrasound devices became the chief representative of the Chinese ultrasound market.

Toshiba Medical System (China) Corporation Ltd was established in Dalian (Liaoning Province) in 2002 and Beijing in 2007 for developing medical imaging devices such as CT, X-ray, MRI and ultrasound. Toshiba set up a R&D base in Dalian in 2013 to further optimize its innovative strength, to produce the medical products, which are fully adapted to the Chinese customers' needs.

7.2.5 The Chinese medical device companies' business activities

(1) Mindray Medical International Ltd. [215] is the largest Chinese medical device manufacturer, which was founded in 1991 in Shenzhen (Guangdong Province). Mindray offers a broad range of products including patient monitoring devices and ultrasound imaging system, a solid distribution network has been established around the world to market their products and services.

(2) Yuwell medical equipment & supply Co., Ltd. [216] is a Chinese listed company founded in 1998 in Danyang (Jiangsu Province). Yuwell is the top brand in the Chinese

homecare medical device industry of 2015. The products including homecare products such as: electronic blood pressure monitor, stethoscope, thermometer and wheelchair, etc.; oxygen supply equipment such as oxygen concentrator, oxygen regulator and oxygen generator and medical imaging device (X-ray).

(3) China Resources Wandong Medical Equipment Co., Ltd. [217] is a state-owned company, which was established in 1955 in Beijing. Wandong is involved in developing, manufacturing and selling of X-ray and MRI devices, which is a leading supplier of medical imaging devices in China. With the fierce market competition, the market share of Wandong in the Chinese high-end medical device market is getting smaller, foreign companies are dominating the market. Therefore, Wandong's products are mainly focused on the low-end medical device market.

(4) Neusoft Medical Systems Co., Ltd. [218] is a leading manufacturer of medical equipment and services, which is the largest healthcare information technology (IT) solutions and services provider, it was founded in 1998 in Shenyang (Liaoning Province). The products including major imaging devices such as CT, MRI, X-ray and ultrasound. Neusoft is the only one Chinese medical device company, which has access to the technology of CT, MRI, X-ray and ultrasound medical imaging devices. Their products have passed ISO 9001 quality management system standards and have FDA and CE mark approval.

(5) Lepu Medical Technology (Beijing) Co., Ltd. [219] is specialized in high-tech medical device manufacturing and selling, which was founded in 1999. Lepu focuses on cardiac therapy, with products including interventional cardiology, prosthetic heart valves, pacemaker and cardiac *in vitro* diagnosis products, etc., it is the largest heart technology manufacturer in China.

(6) MicroPort Scientific Corporation [220] was established in Shanghai in 1998, it is a premier medical solutions provider in China. The products including cardiovascular devices such as coronary stent systems; endovascular devices and orthopaedic devices. Coronary stent products is the first Chinese made drug-eluting stent system, MicroPort is the domestic market leader in the area of coronary stents.

7.3 The Chinese medical device industry core competitiveness analysis

Medical devices are a comprehensive reflection of multi-disciplinary product development. High-margin products require high investment in R&D, market competition requires costly promotion, all this determines that medical devices rely on more investment funding. As a knowledge-intensive industry, human talent gradually become industry's competitive advantage. Therefore, medical device industry core competitiveness can be described as the competition of products, funding and human talent.

(1) Products

The technology innovation of medical device is the key to development. Firstly, medical devices tend towards portability and miniaturization. Secondly, medical devices tend towards digitizing, specialization and networking. For example, the scanning speed, scanning range and clarity of CT has many great breakthroughs in recent years; MRI is

more focused on joint, heart and nervous system's detection and diagnosis; telemedicine requires networking.

Moreover, the treatment of China's top five diseases (cancers; cerebrovascular disease; cardiovascular disease; respiratory system disease and injury, poisoning & external causes) involved medical devices that will bring profitable growth in the future.

(2) Funding

Development of modern high-tech medical devices requires a lot of financial support. For example, in the fiscal year of 2011, Siemens Healthcare R&D spending was USD 1.56 billion, out of USD 16.3 billion in overall company revenue for the year. GE spent USD 4.6 billion for R&D for its different divisions, from this USD 1.3 billion went to GE Healthcare; Philips poured USD 967 million into R&D for its healthcare division [221].

China's R&D expenditures as a percentage of GDP will approach the US levels within 10 years [222]. However, many Chinese medical device companies cannot guarantee enough money for R&D. Some high-tech medical devices like diagnostic imaging devices need a longer R&D period, which means they need more funding to support development. As we said in 7.1, low R&D funding is one of the weaknesses of the Chinese medical device industry, and this is the most important factor, which results in fewer technical patents; low-level repetitive production and low quality products. In the hugely uncertainty R&D stage, it is difficult for companies to obtain loans from banks. Venture capital investment can provide strong financial support to medical device R&D.

(3) Human talent

The competition for human resources is global, especially for critical human talent. China has many universities, colleges and academic institutions, especially the most prestigious universities, which are located in the Bohai Economic Rim, Yangtze River Delta and Pearl River Delta Economic Zones, they provide potential human resources and knowledge-based human talent. Many universities have established and added new courses on medical device research. In addition, many students study in the developed countries and bring the advanced knowledge and practical experience to China. They

contribute to the medical device industry, such as Shanghai MicroPort Scientific Corporation's chairman/founder.

Moreover, the Chinese National Engineering Research Centre established five research centres in Guangzhou (Guangdong Province), Chengdu (Sichuan Province), Beijing, Shenyang (Liaoning Province) and Shenzhen (Guangdong Province) for medical devices R&D. They have many achievements in medical device research and have created significant professional talent that can contribute to China's new companies.

Chapter 8 Conclusion and future work

8.1 Conclusion and findings

The purpose of the study described in this thesis was to understand the *in vivo* diagnostic devices market that is developing and to explore the Chinese medical device market investment potential. The findings presented in this chapter are based on the evidence produced in previous chapters.

(1) Applicable foreign investment theories:

- Related investment theories for developed countries including Hymer's monopolistic advantages theory; Vernon's product life cycle theory, Porter, Hill and Jones's industry life cycle theories and Dunning's eclectic theory of international production.
- Investment theories for developing countries including Wells's small scale technology theory; Lall's technical localization theory; Cantwell and Narula's industry upgrade theory and Dunning's investment development cycle theory.
- Some theories for the medical device industry indicates that research in the medical device market has an upward trend.
- Some related investment theories have been extracted from the foreign investment theory. Little research has focused on the medical device market before, with the development of the medical device industry, literature in this area may increase. Combination of investment theories and medical device market is one of the achievements in this research.

(2) Analysis of the global medical device market:

- Analysis of the global medical device market indicates that top 10 medical device manufacturers are mainly from the US and Europe.
- *In vivo* diagnostics/medical imaging market is dominated by the key manufacturers (GE, Siemens and Philips). They have a strong position in CT, ultrasound, MRI and X-ray market.

(3) Analysis of the Chinese medical device market:

- Official data show that export volume of medical devices and related products is higher than the import volume except for medical diagnosis and treatment, which means China's high-end medical device market is dependent upon imports.
- Some research found that the main medical device market growth drivers are demographics, unmet clinical needs, disease profiles and other drivers like government investment and changed policies. Some of drivers can be examined by mathematical methods. Regression analysis shows that the number of hospital visits, aging population and the number of hospitals are the main drivers in the Chinese medical device market.
- Disease is another driver of the market, especially common cancers. Medical imaging devices which can detect and diagnose common cancers, which means the demand for these kind of devices will increase.
- The key medical device manufacturers' business activities show that the Chinese medical device market has investment potential.

(4) Medical device regulations:

- Medical device regulations across the globe have significant variations. It is important for investors involved in bringing a medical device to market to have an understanding of the regulatory requirements. Analysis of the medical device regulations in the US and EU, demonstrates that the regulation of medical devices is an extremely complex process, because the regulatory authorities have to ensure that the medical devices are safe and effective.
- As the established medical device regulations in the US and EU are relatively mature, they have a key influence in the world. The CFDA released the new medical device regulations in 2014, which is a milestone of the Chinese medical device regulations' history.
- The changes made in the new regulations show the Chinese government's efforts to upgrade and maintain an effective regulatory regime for the medical device market. The new medical device regulations covers various perspectives, such as medical device classification; registration;

supervision of production and distributions; adverse events and recalls; legal liabilities. Many changes cover premarket requirements and postmarket surveillance.

- Few papers focus on the Chinese medical device regulations, because it is relatively new, which came into force in 2014. Therefore, this is another achievement of this research.

(5) The Chinese medical device market investment guidance:

- Previous research shows that the Chinese medical device market has investment potential. Therefore, the investment guidance is important for investors who want to enter the Chinese market. The LQ and MS matrix reveals that the best investment areas in China are Bohai Economic Rim, Yangtze River Delta and Pearl River Delta Economic Zones.
- The LQ method is the first introduced to examine the medical device market. This is one of the achievements of this research.

(6) Competitive analysis of the Chinese medical device market:

- The SWOT analysis describes that the intense competition in the low-end medical device market and the high-end medical device market is dominated by a few foreign companies.
- Regional competitive analysis is an extension of Chapter 6's results. The three economic zones were chosen as the priority areas for investors. These areas have something in common, but also have their own advantages. Regional competitive analysis provides information to investors for location choice in the three economic zones.

The competition in the global medical device market is intense. Industry rivalry is high, and barriers to entry into the market for a young company are high, as market access is controlled by a few standard-setting large companies [4]. Large companies from the US, Europe and Japan accounted for more than 80% of the highly centralized market share. Global *in vivo* diagnostics is a specialty market and dominated by a few large companies.

The medical device industry is one of the fastest growing industries in China. China has become the second largest medical device market in the world, which is only behind the

US market. However, the Chinese medical device market is occupied mainly by foreign companies (such as GE, Siemens and Philips) and high-end medical device market is dependent upon imports, which are mainly import from the US, EU and Japan. When a technological industrial firm in a developed country invests in a developing country (this country should gradually assimilate the economic structure), not only is the knowledge content of the investment important but it will also be directed towards a growth industry [223]. The US, EU and Japanese companies have been able to create an important presence in the newer Chinese medical devices industry; this is because these countries were much more advanced in this technology area than China.

From the analysis in this research, there is no doubt that China is an immense market with many opportunities in the area of medical devices. The best opportunities for foreign investment are in high-tech, high-cost diagnostic devices in the following regions: Bohai Economic Rim, Yangtze River Delta and Pearl River Delta Economic Zones. The market growth drivers (demographics, number of hospital visits, number of hospitals, diseases, government investment and support policies) alongside the new medical device regulations (which came into force in 2014), made the Chinese medical device market more regulated and attractive for the foreign investment.

In summary, this research explored the global medical device market especially for the *in vivo* diagnostics market, identified the key manufacturers in the global market as well as the Chinese market. Detailed analysis of the Chinese medical device market, allows researchers and investors to fully understand the market outlook, regulatory environment and optimum investment strategies. Further research and analysis is required in this area.

8.2 Recommendations

The Chinese medical device market is currently one of the most promising and fastest growing markets with market drivers such as 65+ population and number of hospital visits expanding demand. China's high-end medical device market is dominated by foreign companies, based on this market profile, here are some recommendations for the Chinese practitioners and policy makers.

The Chinese government healthcare reform made the Chinese medical device market develop rapidly. However, the government should pay more attention to scientific and technological innovation, give financial and policy support to companies' innovation, encourage the Chinese companies' R&D on medical devices. To build a national digital medical technology innovation platform, to support the Chinese medical device industry technological innovation and its sustainable development. Moreover, deepen the transnational cooperation with international companies. Increase the training and the introduction of human talent.

Despite the new Chinese medical device regulations which draw on the experience of the international medical device regulations, which have improved many rules, some regulations and policies need continuous modification and improvement due to the changing market environments. For example, the medical device classification rules need further improvement; strengthening the supervision of the medical device market, especially for the high-risk devices.

8.3 Future work

The medical device market is one of the fastest growing industries in the world economy. More and more researchers and investors are getting involved in this area. Following the work in this thesis, there are some research gaps suggested that need to be further investigated:

(1) Literature in medical device investment

Literature in medical device investment will increase in the future. Literature may include foreign investment theories in high-tech areas and review of the medical device market. There are few academic resources (such as journal articles or books) that focus on the medical device market, literature on the medical device market are mainly collected from independent and consulting companies' reports such as Frost & Sullivan and Espicom Business Intelligence and some online resources. Therefore, an increasing body of researchers will get into medical device market research in the future because the medical device market is an expanding market.

(2) Update the relevant data

With the rapid development of the medical device market, the relevant data in this thesis needs to be updated. In this thesis, some of the Chinese government data are hard to access. Data deficiency is a major problem faced by the research. However, the Chinese government is paying more attention on the construction of medical information repositories, the government reports and data on each area are improving.

(3) Medical device regulations

The regulatory information contained in this thesis is subject to frequent change. In order to adapt to the rapid development of science and technology, the existing regulatory frameworks for medical devices must be improved to safeguard public health and ensure the effectiveness of medical devices. Therefore, the updated and latest medical device regulations in the US, EU and China to ensure good medical device performance, safety, quality, must be continuously updated. Additional steps are needed to improve existing policies in the future.

(4) New technological devices

The demand for medical devices in China has remained high over the past few years, the growth trend is expected to continue. The key medical device manufacturers have been working to increase their market share in the mid-end device market in China. For example, as told in Chapter 7, Philips Healthcare set up a joint venture with local software leader Neusoft to capitalize on the demand for mid-end devices, to better meet the needs of Chinese market and other developing countries.

Moreover, non-invasive or less invasive new technological devices such as electrical impedance tomography (EIT)[29], which can be used in common cancers (lung, breast, cervix and brain) detection. In contrast to most other medical imaging techniques, EIT does not apply any kind of ionizing radiation. Even though EIT medical systems have not

[29] EIT is a non-invasive medical imaging technique in which an image of the conductivity or permittivity of part of the body is inferred from surface electrode measurements. (Available from: https://en.wikipedia.org/wiki/Electrical_impedance_tomography.)

been used widely until recently, many medical device manufacturers have been supplying commercial EIT systems (in lung and breast cancer detection) developed by university research groups [224]. Some non-invasive or less invasive new technological devices have investment potential and will occupy some market share in the future. Therefore, research in this area will continue expand.

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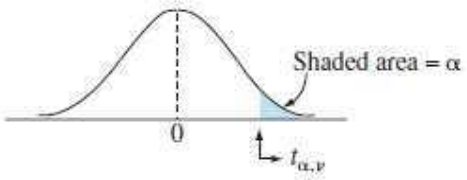
Appendix 1

Percentage points of the t distribution.



df/α =	.40	.25	.10	.05	.025	.01	.005	.001	.0005
1	0.325	1.000	3.078	6.314	12.706	31.821	63.657	318.309	636.619
2	0.289	0.816	1.886	2.920	4.303	6.965	9.925	22.327	31.599
3	0.277	0.765	1.638	2.353	3.182	4.541	5.841	10.215	12.924
4	0.271	0.741	1.533	2.132	2.776	3.747	4.604	7.173	8.610
5	0.267	0.727	1.476	2.015	2.571	3.365	4.032	5.893	6.869
6	0.265	0.718	1.440	1.943	2.447	3.143	3.707	5.208	5.959
7	0.263	0.711	1.415	1.895	2.365	2.998	3.499	4.785	5.408
8	0.262	0.706	1.397	1.860	2.306	2.896	3.355	4.501	5.041
9	0.261	0.703	1.383	1.833	2.262	2.821	3.250	4.297	4.781
10	0.260	0.700	1.372	1.812	2.228	2.764	3.169	4.144	4.587
11	0.260	0.697	1.363	1.796	2.201	2.718	3.106	4.025	4.437
12	0.259	0.695	1.356	1.782	2.179	2.681	3.055	3.930	4.318
13	0.259	0.694	1.350	1.771	2.160	2.650	3.012	3.852	4.221
14	0.258	0.692	1.345	1.761	2.145	2.624	2.977	3.787	4.140
15	0.258	0.691	1.341	1.753	2.131	2.602	2.947	3.733	4.073
16	0.258	0.690	1.337	1.746	2.120	2.583	2.921	3.686	4.015
17	0.257	0.689	1.333	1.740	2.110	2.567	2.898	3.646	3.965
18	0.257	0.688	1.330	1.734	2.101	2.552	2.878	3.610	3.922
19	0.257	0.688	1.328	1.729	2.093	2.539	2.861	3.579	3.883
20	0.257	0.687	1.325	1.725	2.086	2.528	2.845	3.552	3.850
21	0.257	0.686	1.323	1.721	2.080	2.518	2.831	3.527	3.819
22	0.256	0.686	1.321	1.717	2.074	2.508	2.819	3.505	3.792
23	0.256	0.685	1.319	1.714	2.069	2.500	2.807	3.485	3.768
24	0.256	0.685	1.318	1.711	2.064	2.492	2.797	3.467	3.745
25	0.256	0.684	1.316	1.708	2.060	2.485	2.787	3.450	3.725
26	0.256	0.684	1.315	1.706	2.056	2.479	2.779	3.435	3.707
27	0.256	0.684	1.314	1.703	2.052	2.473	2.771	3.421	3.690
28	0.256	0.683	1.313	1.701	2.048	2.467	2.763	3.408	3.674
29	0.256	0.683	1.311	1.699	2.045	2.462	2.756	3.396	3.659
30	0.256	0.683	1.310	1.697	2.042	2.457	2.750	3.385	3.646
35	0.255	0.682	1.306	1.690	2.030	2.438	2.724	3.340	3.591
40	0.255	0.681	1.303	1.684	2.021	2.423	2.704	3.307	3.551
50	0.255	0.679	1.299	1.676	2.009	2.403	2.678	3.261	3.496
60	0.254	0.679	1.296	1.671	2.000	2.390	2.660	3.232	3.460
120	0.254	0.677	1.289	1.658	1.980	2.358	2.617	3.160	3.373
inf.	0.253	0.674	1.282	1.645	1.960	2.326	2.576	3.090	3.291

Source: Computed by M. Longnecker using Splus

Appendix 2

Chinese population and its relevant data from 1980 to 2010.

Year/Ages	China total 65 and above population (millions)	China total population (millions)	Percentages of 65 and above population in China (%)	China total population growth rate (annual %)
1980	50.677	987.05	5.13	1.3
1981	52.697	1,000.72	5.27	1.3
1982	54.594	1,016.54	5.37	1.5
1983	56.419	1,030.08	5.48	1.4
1984	58.218	1,043.57	5.58	1.3
1985	60.009	1,058.51	5.67	1.4
1986	61.565	1,075.07	5.73	1.5
1987	63.149	1,093.00	5.78	1.6
1988	64.754	1,110.26	5.83	1.6
1989	66.377	1,127.04	5.89	1.5
1990	68.05	1,143.33	5.95	1.5
1991	69.808	1,158.23	6.03	1.4
1992	71.671	1,171.71	6.12	1.2
1993	73.608	1,185.17	6.21	1.1
1994	75.58	1,198.50	6.31	1.1
1995	77.576	1,211.21	6.40	1.1
1996	80.073	1,223.89	6.54	1
1997	82.387	1,236.26	6.66	1
1998	84.584	1,247.61	6.78	1
1999	86.749	1,257.86	6.90	0.9
2000	88.912	1,267.43	7.02	0.8
2001	91.044	1,276.27	7.13	0.7
2002	93.202	1,284.53	7.26	0.7
2003	95.336	1,292.27	7.38	0.6
2004	97.312	1,299.88	7.49	0.6
2005	99.087	1,307.56	7.58	0.6
2006	101.237	1,314.48	7.70	0.6
2007	103.21	1,321.29	7.81	0.5
2008	105.163	1,328.02	7.92	0.5

2009	107.325	1,334.50	8.04	0.5
2010	109.845	1,340.91	8.19	0.5

Appendix 3

The predicted Chinese population from 2011 to 2020.

Year/Ages	Total China population (millions)	Total 65+ population (millions)
2011	1,342.32	112.71
2012	1,347.63	115.14
2013	1,353.85	117.61
2014	1,354.77	121.50
2015	1,356.35	125.45
2016	1,359.52	127.99
2017	1,362.93	131.16
2018	1,364.14	135.08
2019	1,363.05	138.37
2020	1,365.06	141.98

Appendix 4

Neural networks.

Neurons	Neural Network Error (res)
4	0.049233
5	0.16097
6	0.048822
7	0.1729
8	0.078508
9	0.114535
10	0.171799
11	0.105598
12	0.166333
13	0.127967
14	0.091731
15	0.047639
16	0.029528
17	0.070366
18	0.111514

Appendix 5

Percentage of Total Deaths of Top 5 Main Diseases in Certain Region from 2003 to 2011(City).

Cause / %	2003	2004	2005	2006	2008	2009	2011
Cancers (Malignant Tumours)	25.47	23.92	22.94	27.25	25.47	27.01	27.79
Cerebrovascular Disease	19.95	19.09	21.23	17.66	19.95	20.36	20.22
Cardiovascular Diseases (Ischemic Heart Disease)	14.43	18.80	17.89	17.10	14.63	20.77	21.30
Diseases of the Respiratory System	14.63	13.12	12.57	13.06	14.63	10.54	10.56
Injury, Poisoning & External Causes	6.16	5.89	8.25	6.10	6.16	5.59	5.47

Source: China Health Statistics, [101, 112-114]

Appendix 6

Percentage of Total Deaths of Top 5 Main Diseases in Certain Region from 2003 to 2011(County).

Cause / %	2003	2004	2005	2006	2008	2009	2011
Cancers (Malignant Tumors)	25.28	23.70	20.29	25.14	25.28	24.26	23.62
Cerebrovascular Disease	23.75	14.85	21.17	20.36	23.75	23.19	21.72
Cardiovascular Diseases (Ischemic Heart Disease)	12.03	12.54	11.77	13.87	12.03	17.21	19.37
Diseases of the Respiratory System	18.72	13.30	23.45	16.40	18.72	14.96	13.31
Injury, Poisoning & External Causes	5.69	6.63	8.47	8.90	5.69	8.25	8.85

Source: China Health Statistics, [101, 112-114]

Appendix 7

Total output value of the medical device industry for each province in China from 2001 to 2011. (Unit: million yuan)

	Beijing	Tianjin	Hebei	Shanxi	Inner Mongolia	Liaoning	Jilin	Heilong-jiang
2001	6047	1896	971	201	22	2671	482	842
2002	8665	2001	935	219	24	3202	516	586
2003	10573	2667	1427	415	---	3683	777	431
2004	13010	3010	1770	530	10	4480	1290	840
2005	16468	3192	2319	1013	---	5526	1031	1023
2006	20131	4184	3003	1155	---	7431	1221	1255
2007	23014	4073	4039	1423	---	10928	1596	1890
2008	21362	5414	3907	1068	41	13650	2686	1541
2009	25380	6209	6248	1380	280	18578	3757	1933
2010	27880	7830	8230	1830	480	22120	5480	2220
2011	29510	6870	9420	2250	340	22420	6380	2080

	Shanghai	Jiangsu	Zhe-jiang	Anhui	Fujian	Jiangxi	Shan-dong	Henan
2001	8887	11888	9640	652	1281	453	3599	924
2002	10281	12361	10315	1186	1703	981	3967	980
2003	10352	14273	14315	1508	2467	963	5133	1018
2004	16320	19580	16270	1920	2680	1710	8150	3120
2005	17923	27863	26238	2482	3044	1947	14738	3570
2006	23569	42435	35956	3122	4057	2891	23518	7431
2007	28305	59261	44851	4364	5065	4527	29345	10505
2008	27739	89171	36779	2688	4524	5589	27610	11968
2009	29403	123423	49546	7873	6199	7478	38905	16945
2010	37040	170830	65870	11070	7900	10540	45010	19600
2011	38480	242270	67160	14570	9940	13430	55080	27820

	Hubei	Hunan	Guang-dong	Guangxi	Hainan	Chong-qing	Sichuan	Guizhou
2001	2413	1404	5045	174	60	2286	816	97
2002	2205	1612	6970	272	52	2531	1079	144

2003	2018	1085	9331	446	18	3282	1395	247
2004	2010	1540	23160	550	10	3780	1730	360
2005	4075	2453	30932	767	3	4343	2444	402
2006	5047	3077	35533	892	---	5231	3976	481
2007	5805	4237	48435	1273	---	6151	5546	668
2008	5138	10724	42586	1550	---	6713	8547	447
2009	6255	13046	42574	2285	---	7935	12549	793
2010	7010	20430	54130	3490	---	12480	8090	730
2011	7200	29390	61060	3630	840	12620	10800	740

	Yunnan	Shaanxi	Gansu	Qinghai	Ningxia	Xinjiang	**Total**
2001	482	1550	154	---	344	12	**65295**
2002	590	1835	192	---	471	7	**75885**
2003	568	1887	340	58	440	27	**91144**
2004	590	3370	250	90	560	50	**132740**
2005	636	3114	257	100	549	83	**178535**
2006	949	4950	229	87	170	86	**242066**
2007	1015	5390	257	129	619	110	**312821**
2008	1101	3350	101	149	629	81	**336851**
2009	1263	7830	287	90	859	127	**439431**
2010	1490	8430	290	100	960	150	**561730**
2011	1190	11490	240	130	1000	100	**688420**

Source: China Statistics Yearbook on High Technology Industry, 2009-12

Appendix 8

Average of total output value of medical device industry for each province in China from 2001 to 2011 (listed in decreasing average value). (Unit: million yuan)

Jiangsu	73941
Zhejiang	34267
Guangdong	32705
Shandong	23187
Shanghai	22573
Beijing	18367
Liaoning	10426
Henan	9444
Hunan	8091
Chongqing	6123
Sichuan	5179
Shaanxi	4836
Anhui	4676
Jiangxi	4592
Hubei	4471
Fujian	4442
Tianjin	4304
Hebei	3843
Jilin	2292
Guangxi	1394
Heilongjiang	1331
Shanxi	1044
Yunnan	898
Ningxia	600
Guizhou	464
Gansu	236
Inner Mongolia	109
Hainan	89
Qinghai	85
Xinjiang	76

Appendix 9

Gross regional product of each province in China from 2001 to 2011.

(Unit: million yuan)

	Beijing	Tianjin	Hebei	Shanxi	Inner Mongolia	Liaoning	Jilin	Heilong-jiang
2001	284565	184010	557778	177997	154579	503308	203248	356100
2002	433040	215076	601828	232480	194094	545822	234854	363720
2003	502377	257803	692129	285523	238838	600254	266208	405740
2004	606028	311097	847763	357137	304107	667200	312201	475060
2005	688631	369762	1009611	417952	389555	786085	362027	551150
2006	787028	435915	1166043	475254	479148	925115	427512	618890
2007	984681	525276	1360732	602445	642318	1116430	528469	710400
2008	1111500	671901	1601197	731540	849620	1366858	642610	831437
2009	1215303	752185	1723548	735831	974025	1521249	727875	858700
2010	1411358	922446	2039426	920086	1167200	1845727	866758	1036860
2011	1625193	1130728	2451576	1123755	1435988	2222670	1056883	1258200
	Shanghai	Jiangsu	Zhejiang	Anhui	Fujian	Jiangxi	Shandong	Henan
2001	495084	951191	674815	329013	425368	217568	943831	564011
2002	574103	1060685	800367	351972	446755	245048	1027550	603548
2003	669423	1244287	970502	392310	498367	280741	1207815	686770
2004	807283	1500360	1164870	475932	576335	345670	1502184	855379
2005	916410	1830566	1343785	537512	656893	405676	1851687	1058742
2006	1036637	2164508	1574251	614873	761455	467053	2207736	1249597
2007	1249401	2601848	1875373	736092	924853	580025	2577691	1501246
2008	1406986	3098198	2146269	885166	1082301	697105	3093328	1801853
2009	1504645	3445730	2299035	1006282	1223653	765518	3389665	1948046
2010	1716598	4142548	2772231	1235933	1473712	945126	3916992	2309236
2011	1919569	4911027	3231885	1530065	1756018	1170282	4536185	2693103
	Hubei	Hunan	Guang-dong	Guangxi	Hainan	Chong-qing	Sichuan	Guizhou
2001	466228	398300	1064771	223119	54596	174977	442176	108490
2002	421282	415154	1350242	252373	62197	199001	472501	124343
2003	475745	465999	1584464	282111	69320	227282	533309	142634

2004	563324	564194	1886462	343350	79890	269281	637963	167780
2005	652014	651134	2236654	407575	89457	306692	738511	197906
2006	758132	756889	2620447	482851	105285	349157	863781	228200
2007	933340	943960	3177701	582341	125417	467613	1056239	288411
2008	1132889	1155500	3679671	702100	150306	579366	1260123	356156
2009	1296110	1305969	3948256	775916	165421	653001	1415128	391268
2010	1596761	1603796	4601306	956985	206450	792558	1718548	460216
2011	1963226	1966956	5321028	1172087	252266	1001137	2102668	570184

	Yunnan	Shaanxi	Gansu	Qinghai	Ningxia	Xinjiang
2001	207471	184427	107251	30095	29838	148548
2002	231282	225339	123203	34065	37716	161265
2003	255602	258772	139983	39020	44536	188635
2004	308191	317558	168849	46610	53716	220909
2005	347289	377269	193398	54332	60626	260419
2006	400672	452374	227670	64158	71076	304526
2007	477252	575729	270240	79735	91911	352316
2008	569212	731458	316682	101862	120392	418321
2009	616975	816980	338756	108127	135331	427705
2010	722418	1012348	412075	135043	168965	543747
2011	889312	1251230	502037	167044	210221	661005

Source: National Bureau of Statistics of the People's Republic of China, 2012

Appendix 10

Gross domestic product of China from 2001 to 2011. (Unit: million yuan)

2001	10965520
2002	12033270
2003	13582280
2004	15987830
2005	18493740
2006	21631440
2007	26581030
2008	31404540
2009	34090280
2010	40151280
2011	47288160

Source: National Bureau of Statistics of the People's Republic of China, 2012