

Real breakthrough into Medical Devices Market of China

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Agenda

- Chinese Market Overview
- Potential Opportunities
- Market Status Quo
- Barriers and Gaps
- About NCCBA and Proposed Service

China's Medical Devices Market Overview

■ A Market You Cannot Ignore

- Largest population in the world (1.3 billion people)
- \$ 6.4 – 10.6 * billion medical device market (2004 estimation) and growing 15% annually—double the growth rate of the industry worldwide
- Highly fragmented market
 - More than 6,600 medical device manufacturers operating in China without dominant players
- Immediate demand for technologically advanced equipment, devices, and services from developed countries, i.e. the United States and Europe
- As a member of the WTO, China abides by the same standardized patent protection laws as the United States and Europe

*: Due to different sources and definition of medical devices

Potential Opportunities

- Fast developing healthcare market
 - In 2004, the Chinese government has pledged to invest additional \$36 billion in healthcare expenditures over the next four years
 - Substantial demand from fast expanding middle class
- More open market in post-WTO entry era
 - Lower tariff: ca. 3.9% since January 1, 2005
 - Relaxed restriction on foreign investors
 - Allowing investment in distribution

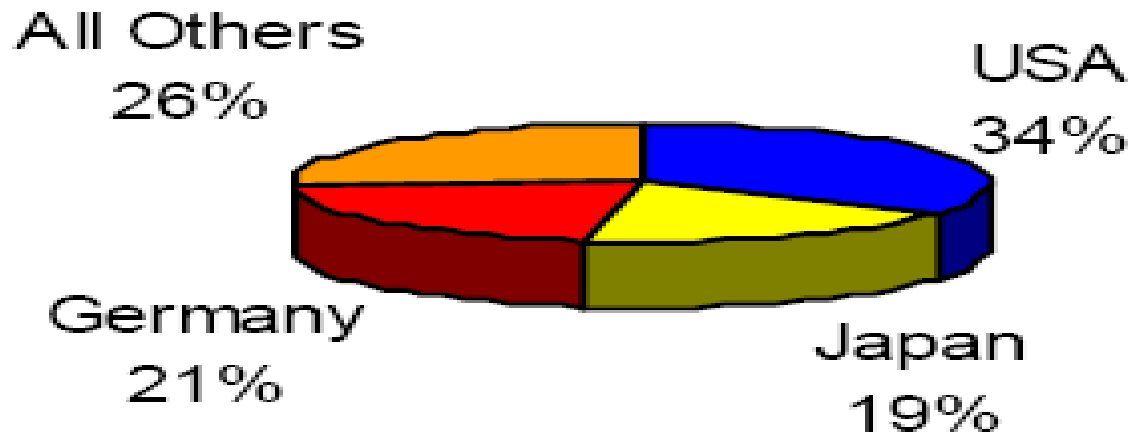
Potential Opportunities

- Huge unmet needs
 - The nation's domestic medical device industry produces less than half of what the market needs
 - Inability to produce advanced medical devices domestically
- High autonomy of hospitals
 - Almost all major hospitals are state-owned-enterprises (SOEs)
 - SOEs are independent and enjoy autonomy for making purchase decision
 - Financial incentive to buy: self finance system

Status quo

- China's Medical device import market share

2002

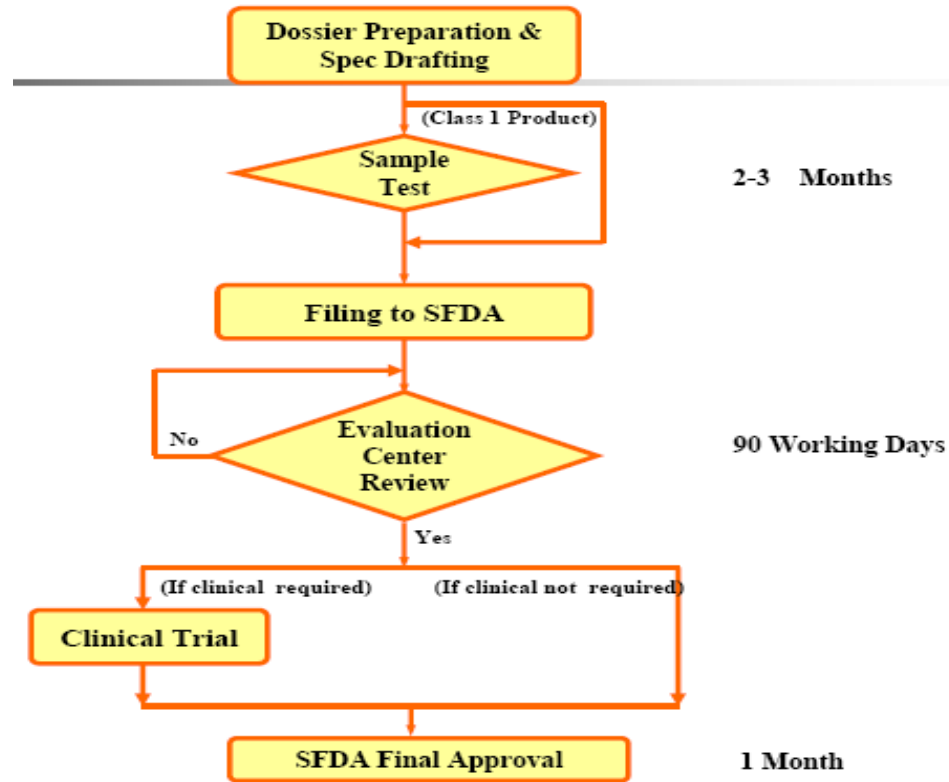


Source: China's Customs Statistics

Medical Devices Classification

- China's regulatory agency SFDA (State Food and Drug Administration), in many ways, follows the regulation of FDA in the U.S.
- Accordingly, medical devices are split into three categories, each with specific regulatory requirements.
 - Class I: Low risk devices, regulated by provincial governments
 - Class II: Modest risk devices, regulated by provincial governments
 - Class III: High risk devices, regulated by the SFDA

Medical Device Registration Process



Class	I	II	II	III	III
Clinical Trial*	N/A	no	yes	no	yes
Time (Months)	5-6	7-8	12-14	7-8	12-14

* Clinical Trials: 100 cases, 2-3 SFDA designated clinics

Barriers

Regulatory Environment

- Frequently changing, becoming confusing and complicated
- Multiple regulatory bodies for medical equipment
 - SFDA
 - CNCA (Chinese National Certification and Accreditation Administration)
 - *Applicable to some products*
 - AQSIQ (General Administration of Quality Supervision, Inspection, and Quarantine)
 - *Applicable to some products*
 - Other administrative agencies, local regulatory agencies, and other product specific regulation

Barriers

Complicated distribution networks

Export Distribution Structure



Barriers

Regionalized China

Three different Areas



Barriers

Regionalized China

The Wealthiest Consumers in China

GDP per capita (US\$) in 2001

Pearl River Delta		Yantze River Delta	
Shenzhen	5238	Shanghai	4516
Guangzhou	4592	Wuxi	3775
Dongguan	4564	Suzhou	3671
Foshan	3863	Hangzhou	3029
Zhuhai	3541	Nanjing	2488

Barriers

Difficult to predict market

- The potential hurdles to medical device exporters
 - Complex product registration processes
 - i.e. arbitrary test requirements
 - Complicated business environment
 - Restrictions on the types of business activities foreign firms can engage in
 - Local procurement policies

Barriers

Complicated Business Environment

- Promoting medical devices need trust, support, education and maintenance
- "Good network 'guanxi' for local deal sourcing and business know-how in China is key"
- Alliance with local partners will speed up the learning curve and limit risk at the same time

Disadvantage for Foreign Companies

- Particularly for small to middle size companies
 - Different economic situation and mindset of business
 - Constrained resources
 - Lack of economies of scale
 - Unfamiliarity of foreign local market
 - Informal, social and cultural constraints
 - Political and financial risks

Huge untapped potentials in NC

- North Carolina
 - One of medical device zones
 - Many dynamic small to middle size companies facing severe competition in domestic market
 - Not fully developed potential
 - Evidenced by findings from NC Department of commerce: medical device has no specific data
 - No emphasis on international trading

Who we are

Introduction of NCCBA (North Carolina Chinese Business Association)



North Carolina Chinese Business Association
北卡州華人企業協會

Monday 30. May 2005

Home About NCCBA Services Resources Help & Support

Web Search

Member Services Area:

If you would like to be on the NCCBA mailing list, please follow this link.

Current Member Login

New member? Please register here.

Upcoming Events:

1. On May 31st

Welcome...

Dear friends,

As you may know, North Carolina Chinese Business Association (NCCBA) has just been established. As a premier nonprofit charitable and educational business organization, NCCBA's mission is to represent, serve, and promote the common interests of our membership and the North Carolina Chinese business community, particularly in promoting entrepreneurial and corporate development related to science and technology.



NCCBA serves as a forum for networking and exchanging, for advancing our knowledge in creating and sustaining successful businesses, and for encouraging and facilitating coaching and consultation among our members. NCCBA will also serve as a major catalyst in bridging the China - North Carolina business relationship.

Please join us and work together to advance the business spirit of North Carolina's Chinese community.

Frank Wang, President, NCCBA

- NCCBA (<http://www.nc-cba.org>) is premier nonprofit charitable and educational business organization, striving to serve as a major catalyst in bridging the China - North Carolina business relationship.
- NCCBA proudly has talented people with solid background, hand-on experience and strong network in China's healthcare industry, such as pharmaceutical (biotech), medical devices, and hospitals

Services we propose

- Instead of lip service, NCCBA will open a branch office in China to consolidate all the resources to specifically promote medical device products manufactured in NC to help local economy
- Services include, but not limited to
 - Registration
 - Market development and penetration
 - Trade mission
 - Market research
 - Clinical trial
 - Marketing strategy formulation
 - Marketing strategy implementation

Services we propose

Where we are

