



Discover Global Markets Life Science

China Medical Device Market Opportunities & Barriers

Angela Han

*Senior Commercial Specialist
Commercial Service Guangzhou*



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China Market Overview



Market 17 B – 2013 (0.2 : 1 vs. pharm.)

Number 3 market in the world



U.S. : China's leading supplier of medical devices



China: US 6th largest export markets

China Market Overview



- Devices manufacturers: 15,961
- YRD- disposable injection & infusion
- Bohai – CT, MNC
- Shenzhen hi-end medical device - imaging, blood analyzer, patient monitoring

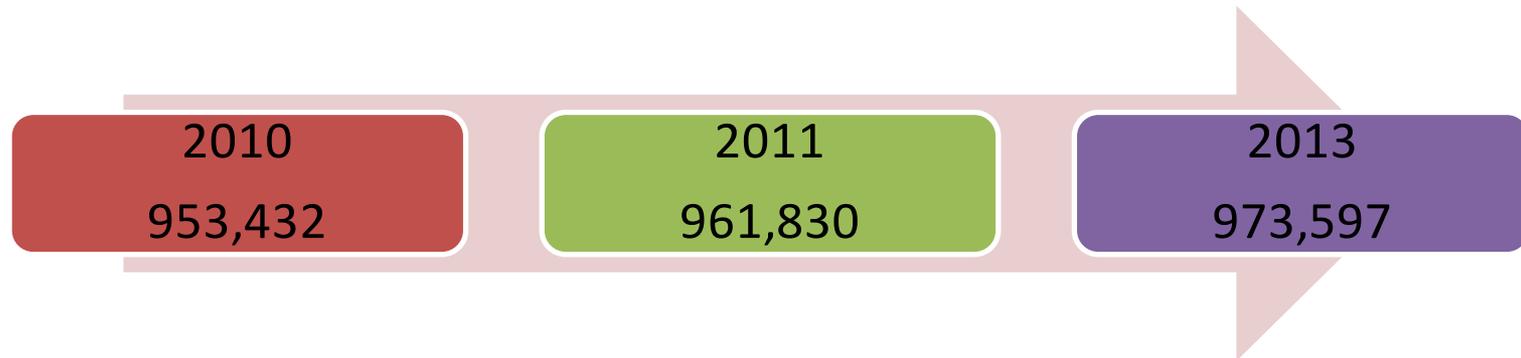


Distributors: 160,000

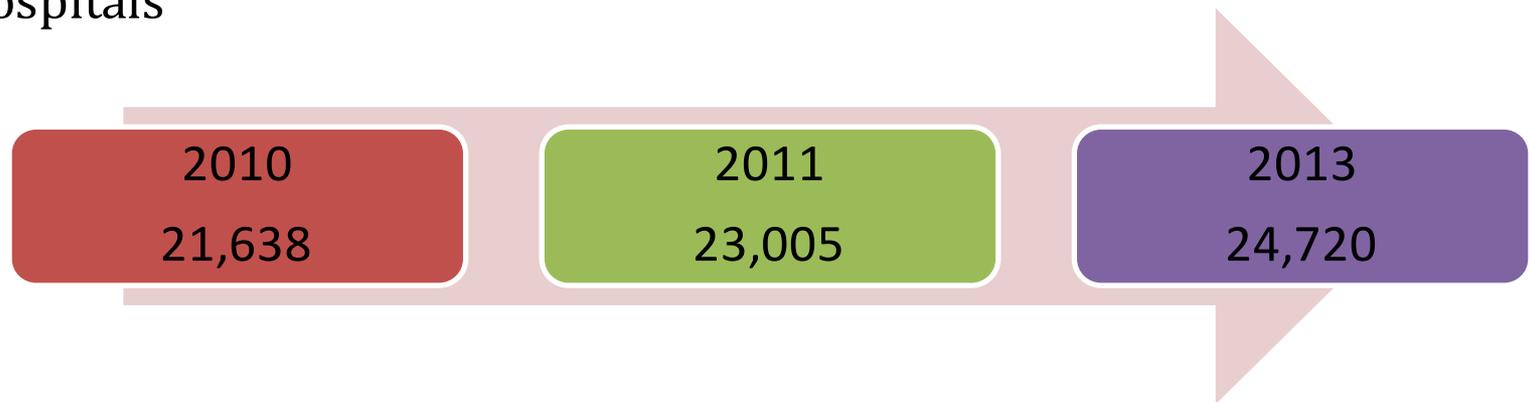


China Market Overview

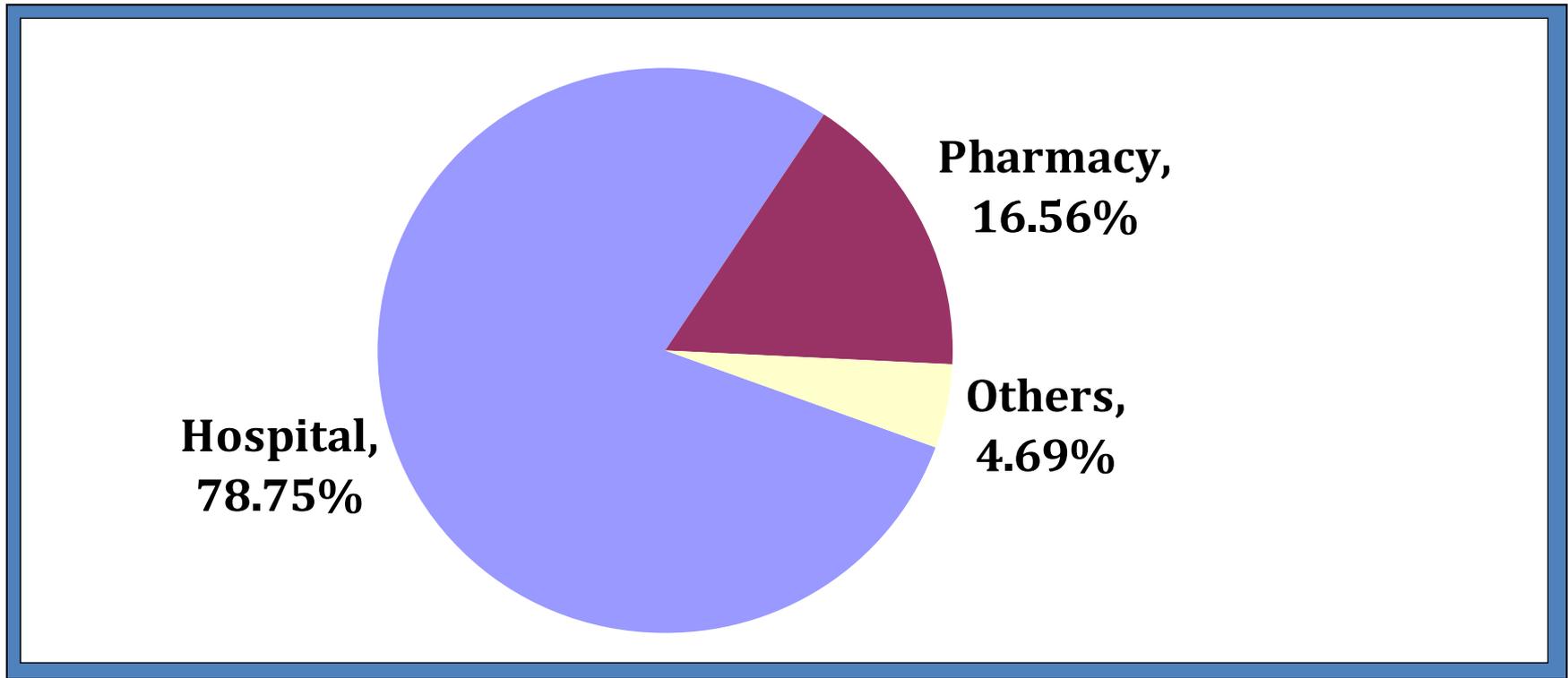
Medical and Health Institutions, clinics



Hospitals

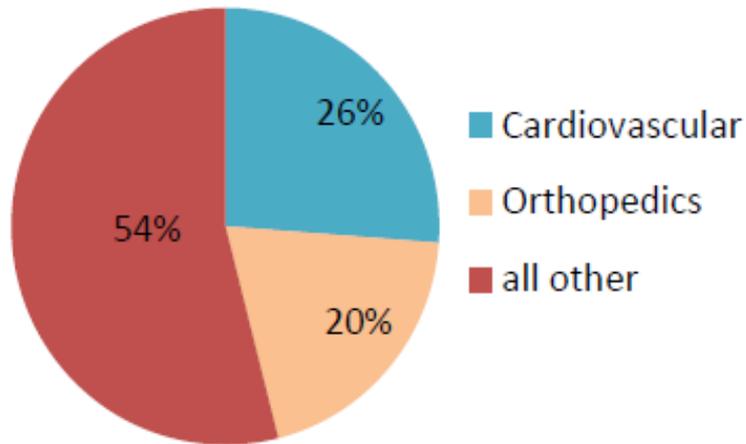


China Market Overview - Channel



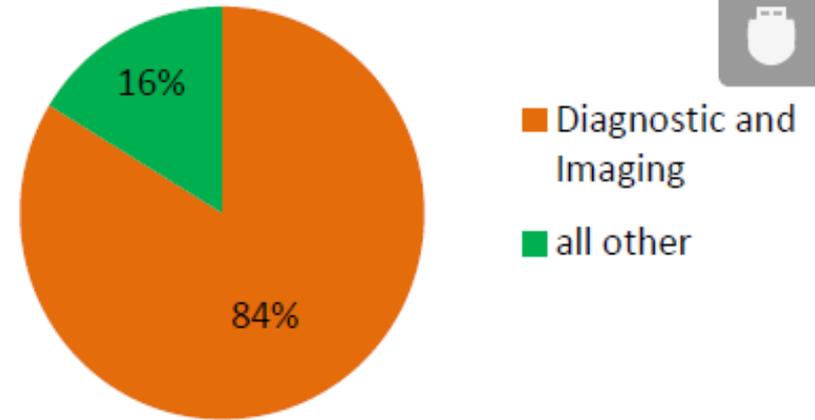
Other – 4.69% (specialty store, community sale, e-commerce, department store etc.)

U.S. export mostly diagnostic&imaging, orthopedics and cardiovascular products to China in 2013



IMD EXPORTS

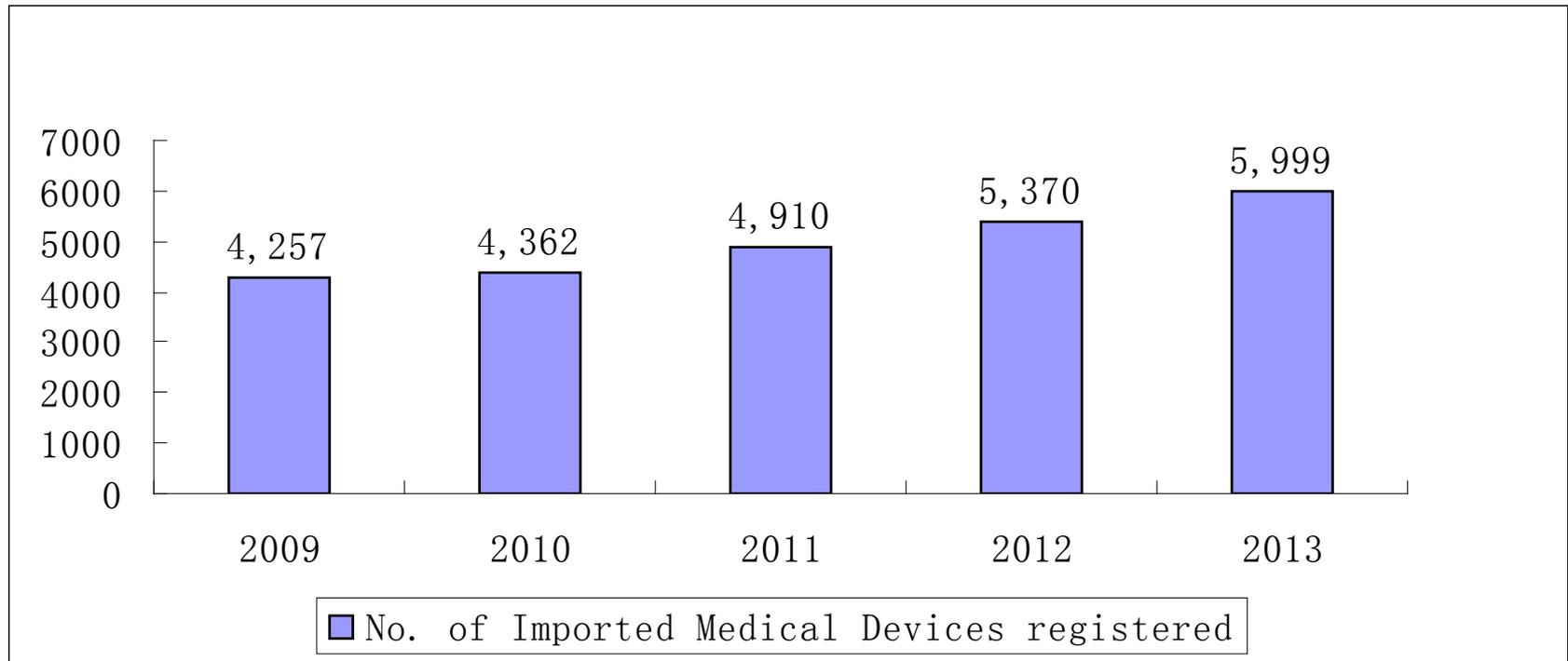
2013 Total: \$767 million



Non-IMD EXPORTS

2013 Total: \$1.7 billion

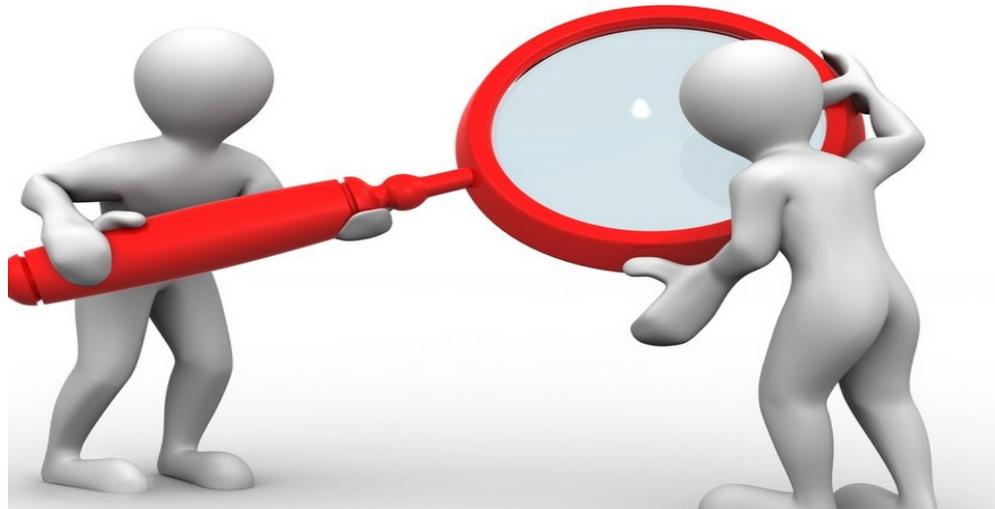
CFDA Registration of Import Medical Devices (2009-2013)



More foreign medical devices are imported into China over the past five years.

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Updates on the new regulations that came into effect since 1st Oct, 2014



Main Changes from CFDA Regulation

<i>After change</i>	<i>Before change</i>	<i>Remarks</i>
<i>Class I - filing</i>	<i>Registration required, almost same as class II and III</i>	<i>Shorter registration time</i>
<i>Clinical trials required for class II and III unless exempted</i>	<i>Import devices are usually exempted for clinical trails</i>	<i>Big challenge to import device</i>
<i>Pre-approval of CFDA is required for clinical trials of high risk class III devices</i>	<i>Not needed</i>	<i>Longer registration time</i>
<i>Large & heavy equipment must be tested before registration application is submitted to CFDA</i>	<i>May be tested after approval of registration</i>	<i>Longer registration time</i>
<i>Innovative device may apply for registration before massive production.</i>	<i>Applicant who submit for registration must have got manufacturing license</i>	<i>Good for local company</i>
<i>Time line of technical evaluation for class III device is prolonged to 90 working days</i>	<i>60 working days for class II and III</i>	<i>Longer for class III device</i>
<i>Registration validity - 5 years</i>	<i>4 years</i>	<i>Good change</i>
<i>CFDA registration fee required, amount not decided</i>	<i>No fee since 2004</i>	<i>Cost more</i>
<i>Require Legal Agent & After Sales Agent</i>	<i>Only require Legal Agent</i>	<i>More responsibility</i>

Challenges

Regulation barriers

- Registration & Clinical trial
- Certificate of free sales

Public Bidding

Reimbursement

Increasing local competition

IPR infringement

Clinical trials and Pre-approval

	<i>Before Change</i>	<i>After Change</i>
<i>Import device</i>	<ul style="list-style-type: none"> - Not required in China - If required in country of origin, clinical trials report or clinical literature evaluation can be provided; 	<ul style="list-style-type: none"> - Required if not in the exemption list or application for exemption not approved - May apply for exemption case by case - Pre-approval for clinical trials of high risk devices
<i>Impact Financial cost</i>	<p style="text-align: center;"></p> <p>\$ 0.5-1.5 millions for each for imaging or radiotherapy equipments. \$300-700K clinical evaluation or supplementary trials even if exemption</p>	
<i>Time delay</i>	<p>19 months : 4 months for pre-clinical approval ①, 15 months for clinical trials, shortage ② of clinical resource</p>	

Note ①: if the device is totally new to China market, or in the list of high-risk devices, it needs pre-approval.

②: constrains of clinical resources including patient, clinical centers, and research professional

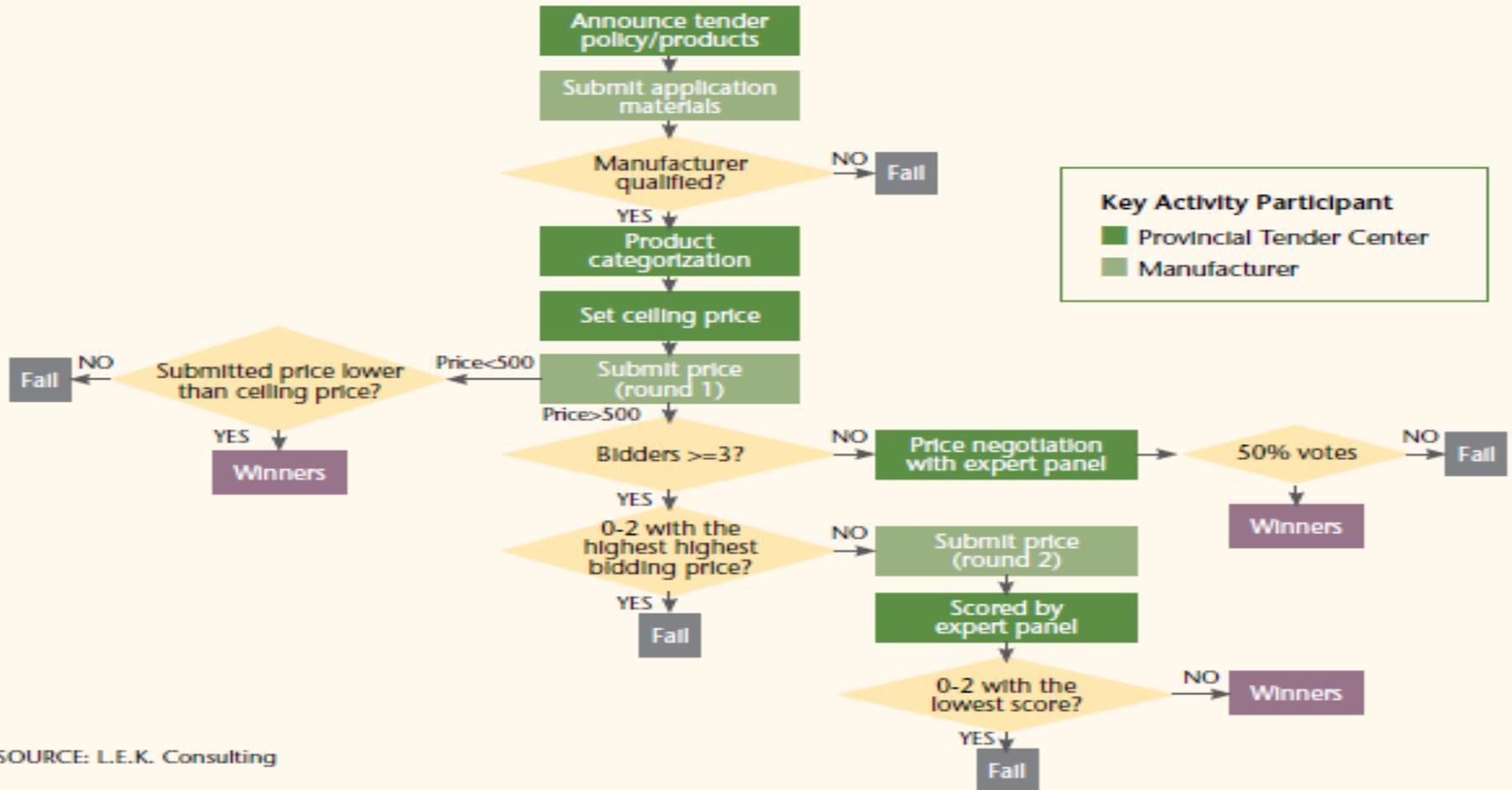


Pre-requisite for import

	<i>No change, but impact on import product remains</i>
<i>Import device</i>	<ul style="list-style-type: none"> - <i>Market approval in the country of legal manufacturer</i> <i>Or</i> - <i>Market approval in the country where the product is physically manufactured</i> 
<i>Impact: Restriction</i>	<i>Not allowed for market approval in China if not been approved by US FDA or not legally marketed in the country where the device is manufactured physically</i>
<ul style="list-style-type: none"> • <i>Time delay</i> 	<i>6 months delay to wait for US FDA 510k approval, or even 24-36 months for FDA PMA approval before submission for China.</i>
<ul style="list-style-type: none"> • <i>Excluded from expedite channel</i> 	<i>Need IP submission or registration in China;</i> <i>Hard to qualify for innovative product;</i> <i>Pre-approval for market in US prevent earlier processing of CFDA</i>

Complicated bidding process

Beijing Medical Device Tender Process



SOURCE: L.E.K. Consulting

Opportunities



MD market underdeveloped

- 14% of healthcare vs. 40% in foreign countries
- Per capita among the lowest

Largest aging population - senior care, chronic disease

Healthcare reform – more hospitals, more investment

-Shenzhen: 20 new hospitals by 2020

-Guangzhou: 10+ new, 30+ expansion by 2015

E-commerce?



What the Chinese Want

Hospital management, doctor's training

Cardiovascular diagnosis and treatment : prosthesis, stents, intervention kits, ambulatory blood pressure monitor, continuous glucose monitor, non-invasive glucose monitor etc.

Oncology diagnosis and treatment

Ultrasound

Gynecological diagnosis and treatment

IVD

Orthopedics products, such as joint prosthesis

Nutritional supplements, ingredient

Local partners

- AdvaMed
- Amcham HCP
- MITA
- Commercial Service
- Local medical associations (CAMDI, Shenzhen Medical Devices Association, etc.)
- Local healthcare bureaus/department

Upcoming Events – South China

Trade shows – CMEF, Dental South,
Pharm China, etc.



USG programs - Roadshows (GZ/FJ/HN)

- Healthcare Technology (IVD & Chronic Disease Treatment)
(December 18, 2014)
- * Tumor / Cancer treatment - 2015 Spring



Question?

Contact:

Angela.han@trade.gov

Tel: +86 -20- 3814 5543

Commercial Service Guangzhou,
China