REGULATORY REQUIREMENTS FOR MEDICAL DEVICES IN THAILAND

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FDA THAILAND

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Products in Control of Thai FDA

- Food, Drugs, Psychotropics Substances, Narcotics, Volatile Substances
- Medical Devices
- Cosmetics
- Hazardous substances for household use
Infra-structure of Food and Drug Administration

Secretary-General

Committees

- Food Control Bureau
- Drug Control Bureau
- Medical Devices Control Division
- Narcotic Control Bureau
- Cosmetic and Hazardous Substances Control Bureau
- Import and Export Inspection Bureau

Office of the Secretary

- Technical and Planning Bureau
- Internal Audit Task Group
- Legal Group

3 Deputy Secretary Generals

- Public & Consumer Affairs Division
  - Rural and Local Consumer Health Product Promotion Division
- Information Technology Center
  - National Program on Chemical Safety
- Public Sector Development Group
  - OSSC, Enforcement Center Complaint Center
"Excellent organization to protect public health and promote the use of health products which are safe, cost-effective and in good quality, leading to healthy society."
THAI FDA VALUE

“PROTECT”

- P - People Centric
- R - Reliability
- O - Ongoing Learning
- T - Team work
- E - Ethic
- C - Competency
- T - Transparency
MEDICAL DEVICE ACT IN THAILAND

• Before 1988, using Drug Act

• Since May 1988 - Medical Device Act 1988 (effective date: 6 March 2008)

• Medical Device Control Division, Food and Drug Administration was officially established in June 1990 as regulatory authority to control manufacturing, importing, selling and advertising of medical devices in Thailand.
DEFINITION OF MEDICAL DEVICES (1)

- include Medical Devices
  - include IVD products
  - include Software

For Animal Use
• include accessories, components or parts of medical devices

• include any products announced by the Minister to be medical devices
The medical devices must not achieve its primary intended action in or on the human or animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
CONTROL OF MEDICAL DEVICES

• Pre-market approval
• Control at port by FDA inspectors with close relation with custom officers
• Postmarketing surveillance and vigilance
• Advertisement control
• Communication of risk information to the public
1. Establishment Registration:
   - Manufacturing Registration
   - Importing Registration

2. Selling License for some medical devices
Medical Devices are classified into 3 groups:

- *Licensed Medical Devices*

- *Notified Medical Devices*

- *General Medical Devices*
1. Licensed medical devices
2. Notified Medical Devices
3. General Medical Devices
Post-Marketing Control of Medical Devices

- premise regular inspection
- product sampling check, recalling system
- cease production, importation and distribution
- AE reporting and vigilance system
- law enforcement
- public education and awareness
One Stop Service Center in Thai FDA

- Pre-marketing service for all FDA responsible health products: medical device, drug, food, cosmetic, hazardous substances (except narcotic and psychotropic drugs)
- Pre-advertisement approval
- Issuing Certificates, etc
One Stop Complaint Center in Thai FDA and Adhoc Post-market Team

• Post-marketing service for all FDA responsible health products

• Post-advertisement control/monitoring

• Law enforcement
Network of Control

- Provincial FDA operated by provincial health offices
- Inspection at FDA port situated among all regions and work closely with Custom Department
- Network of Expertise, Lab/Test Agency, Standard organization, Health Professional Associations, etc
Licensed Medical Devices

- **Condoms**
- **Surgical Gloves (being reclassified)**
- **Examination Gloves (being reclassified)**
- **HIV test kit for diagnosis**
- **Corrective and Cosmetic Contact Lens**
Notified Medical Devices

- Physical Therapy Devices
- Alcohol Detectors
- Silicone Breast Implants
- Breast Enhancer External Use devices
General Medical Devices

• Devices not on the list of Licensed medical device and Notified medical device

• Majorities are general medical devices
• *Ministerial Notification:* Requirements on Recording and Reporting of manufacturing/importing/selling of medical devices dated 7 June 2011
• Ministerial Regulations and FDA Notifications on Application and Issuing of Manufacturing/Importing Medical Device Products Licenses and Notifications dated 28 May 2012

--- CSDT Requirements
FUTURE PRIORITY PLANS (1)

Reclassification and Control Level of Medical Devices based on Risk Factor

- Medical devices (Non IVD)
- IVD devices
1. Licensed medical devices → High Risk
2. Notified Medical Devices → Moderate Risk
3. General Medical Devices → Low Risk
FUTURE PRIORITY PLANS (2)

National Single Window/ License

per invoice
Target Thai FDA License per invoice Medical Devices

October 2012
December 2012

Target ASEAN All Health Products

January 2015
Thai FDA

Custom Department
## Database Importers

<table>
<thead>
<tr>
<th>Importer (Company) Registration Number</th>
<th>ID code</th>
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</table>


Database Medical Devices (1)

<table>
<thead>
<tr>
<th>Product License No</th>
<th>Product Notification No</th>
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</thead>
<tbody>
<tr>
<td>FDA Import Permit Letter for General Medical Devices No</td>
<td>No</td>
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Database Medical Devices (2)

<table>
<thead>
<tr>
<th>Custom (HS) Code</th>
<th>Product Code</th>
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</thead>
<tbody>
<tr>
<td>City and Country of Origin/Manufacturers</td>
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</table>
Duties of Importers

• input product database for all items that are still active or planned to be sold in Thailand

• pilot implementation

• full scale implementation
FUTURE PRIORITY PLANS (3)

ASEAN Medical Device Directive

and AEC 2015
FUTURE PRIORITY PLANS (4)

Continue to draft or amend regulations e.g.

- **Ministerial Notification No. 34, 19 July 2006** “Medical Devices to be prohibited for import and sale”

- **FDA rule 2007, 28 February 2007** “Principles on Certification required for import approval of medical devices”
FUTURE PRIORITY PLANS (5)

Outsource Program