Medical Devices Registration (Filing)

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Statement

This presentation is a personal point of view, does not represent any official interpretation.
The Structure of Regulations for medical devices

- **Regulations**
  - e.g. Regulations For Supervision and Administration of Medical Devices

- **Departmental Rules**
  - e.g. Measures for the Administration of Medical Device Registration

- **Normative Documents**
  - e.g. Catalog of Medical Device Classification
    - Guidelines for Technology Review of Registration

Legal basis of registration and filing

- Class I medical devices are for filing management and Class II and Class III devices are for registration management
  - (Article 8, No.650 Decree of the State Council of the People’s Republic of China, 2014)

- Medical devices which will be marketed or used within the territory of the People’s Republic of China shall apply for registration or for filing in accordance with the Measures for the Administration of Medical Device Registration (Item 2, Order No.4, 2014)
**History of regulations reflect the changing environment**

---|---|---|---
Manufacturer: less than 5k | Manufacturer: 16k | Output: ¥ 30 billion | Output: ¥ 400 billion

**Basic requirements**

- More restrict & sophisticated
- More risk based & scientific system

**Risk Based Classification**

Facts to evaluate the degree of risks of a medical device:

- Intended use
- Structural characteristics
- Method of use
- Other considerations
Class I Medical Devices

The medical devices with lower risks are categorized as Class I medical devices; their safety and effectiveness can be guaranteed by implementing general management.

Class II Medical Devices

The medical devices with moderate risks are categorized as Class II medical devices. Their safety and effectiveness can be guaranteed by implementing stricter management.
Class III Medical Devices

The medical devices with higher risks are categorized as Class III medical devices, their safety and effectiveness can be guaranteed by taking special measures and by stricter management.

Comparison of Classification of Devices

<table>
<thead>
<tr>
<th>Classification of Devices</th>
<th>China CFDA*</th>
<th>US FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>38%</td>
<td>46%</td>
</tr>
<tr>
<td>Class II</td>
<td>35%</td>
<td>47%</td>
</tr>
<tr>
<td>Class III</td>
<td>26%</td>
<td>7%</td>
</tr>
</tbody>
</table>

Example: single-use syringe is a class II in US but class III in China

Note*: According to CFDA Medical Device Classification catalog of 2000
How to know the classification of a medical device?

- Find it in The *Catalog of Medical Device Classification*
- If you could not find it:
  - Directly apply for the Class III Medical devices registration
  - Determine the classification according to the *Classification Rules* and submit an application to CFDA (20wk days)

### Major difference between Classes

<table>
<thead>
<tr>
<th></th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathway to the market</td>
<td>Filing</td>
<td>Registration (approval)</td>
<td></td>
</tr>
<tr>
<td>Timeline</td>
<td>On the Spot</td>
<td>At least 90 Wk Days</td>
<td>At least 120 Wk Days</td>
</tr>
<tr>
<td>Clinical requirements</td>
<td>Clinical trial is not required</td>
<td>Clinical trials are required , in qualified institutions, Exemption list(for Class II class III), Pre-clinical approval for hi-risk device</td>
<td></td>
</tr>
<tr>
<td>Test requirements</td>
<td>Self testing report is acceptable</td>
<td>Full performance test of the final product , by CFDA accredited test centers</td>
<td></td>
</tr>
<tr>
<td>Period of validity</td>
<td>Do not set the period of validity</td>
<td>5 years, need renew</td>
<td></td>
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</table>
Division of authority: Local FDAs and CFDA

For Domestic Devices
- Class I: Local FDA of city level
- Class II: Local FDA of provincial level
- Class III: CFDA

For Imported Devices
(And Devices from Hong Kong, Macao, Taiwan)
- Class I to Class III: CFDA

For example: Beijing FDA is a Local FDA at the provincial level (Beijing a municipality directly under the central government)

The Registrant and agent

- Registrant of medical device is an enterprise that put the product into market in its own name and bear legal responsibility for the product

- The overseas registrant shall carry out the relevant work through its representative body or a domestic enterprise in China as an agent.

- An agent also take joint responsibilities
Basic Data lists for Registration and filing

- Risk analysis data
  (Based on YY/T0316-2008 (Chinese eq of ISO 14971:2007))

- Technical requirements
  (Mandatory standards, Guidelines for Technology Review of Registration)

- Test reports
  (final product, based on Technical requirements)

Basic Data lists for Registration and filing

- Clinical evaluation data
- Product manual and label sample
  (Provision of medical device instruction for use and labeling)
- Quality management system documents
- Other data
  (e.g. Evaluation data, List for basic requirements of safe and effective of Medical devices)
Notice these points

- Must using Chinese language
- Product Name requirement (using generic name)
- Market approval from the country of applicant (registered address or address of manufacturing site)

Typical Flow Chart for Registration of Class II and Class III devices

- Product Development
- Technical Requirements
- Registration Test
- Clinical Trial
- Data Aggregation
- Submit Application
- Application Accepted
- Technical Evaluation
- Administrative Approval
- Registration Certificate

- Site inspection
- Data Correction
- Supplement information

- 1 year
- 5 Wk days
- 60 Wk days
- 60 Wk days (II)/90 Wk days (III)
- 20 Wk days
- 10 Wk days
- 3 Wk days
Thank you!