Harmony with Strength
Global trends in regulatory reform

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6th CIMDR
Guangzhou, September 2015
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securing your compliance

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2015 – Council Adopts draft regulation for final discussions
Europe – What’s Changing

Clinical Evidence
- Trials mandated for Class III
  - Manufacturers may consult expert panel on strategy

Fewer, better Notified Bodies
- Stronger accreditation criteria
  - Stricter process – with central oversight
  - Unannounced inspections

Stricter rules on Authorized representatives
- Greater competence
  - Product liability

Classification update
- Adjustment of Class III
  - Software
  - Accessories

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Europe – What’s NOT changing

- Essential Requirements
- Risk Based Classification
- 3rd Party Assessment
- Risk based review
- Use of standards

The Fundamental Regulatory Model is unchanged
Australia: Expert Review of Medicines and Medical Devices Regulation

- Stage 1 Report on Medicines and Devices published June 2015
- 32 recommendations
  - Principles for regulation
  - Pre-market approvals
  - Post-market monitoring
  - Access to unapproved therapeutic goods
  - Structure
Australia – Recommended Changes

- Don’t change the system
  - Classification, Essential Principles, Risk based assessment

- Clear Rationale for any unique requirements

- Streamline/reduce Class I devices

- Expand 3rd Party

- Utilise approvals by Comparable authorities

- Expedited pathway for new technologies

- TGA develop transparent criteria for designation of 3rd parties

- Stronger postmarket
  - use of registries, international sharing of data

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Past Proposal for “Class IIb” 510(k)

- Require clinical data

Expedited pathway
Japan 2014: PAL becomes PMDL

- 3rd Party Assessment widened
  - Most Class II
  - Some Class III
  - Standards based

- Harmonized GMP (ISO 13485)
  - Removed most local requirements
  - Abolished manufacturer licensing

- Increased supervision of Authorised representatives
  - Including GMP audit
  - Adjusted classifications and definitions
    - Software

- Streamlined Change controls
  - Simpler variation submissions,
  - Widening of design controls
Key Elements of China Reforms

- Classification Rules
- User Fees
- Chinese STED
- Local Clinical Trials
- Expedited Pathway
## Medical Device Classification Table

<table>
<thead>
<tr>
<th>Non-active Medical Device</th>
<th>Body Contact Devices</th>
<th>Active Medical Device</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Transient</td>
<td>Short-term</td>
</tr>
<tr>
<td></td>
<td>Skin</td>
<td>Trauma</td>
</tr>
<tr>
<td></td>
<td>/Body Orifice</td>
<td>/Tissue</td>
</tr>
<tr>
<td>(Stoma)</td>
<td>(Stoma)</td>
<td>(Stoma)</td>
</tr>
<tr>
<td>1 Fluid delivery devices</td>
<td>I</td>
<td>II</td>
</tr>
<tr>
<td>2 Modify blood, body fluid devices</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>3 Dressing</td>
<td>I</td>
<td>II</td>
</tr>
<tr>
<td>4 Invasive devices</td>
<td>I</td>
<td>II</td>
</tr>
<tr>
<td>5 Reusable, surgical devices</td>
<td>I</td>
<td>I</td>
</tr>
<tr>
<td>6 Implant devices</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>7 Contraception and pregnancy planning devices (Exclude reusable non-active surgical device)</td>
<td>II</td>
<td>II</td>
</tr>
<tr>
<td>8 Other non-active</td>
<td>I</td>
<td>II</td>
</tr>
</tbody>
</table>

### Active Medical Device

<table>
<thead>
<tr>
<th></th>
<th>Mild Damage</th>
<th>Moderate Damage</th>
<th>Severe Damage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Energy therapy devices</td>
<td>II</td>
<td>II</td>
<td>III</td>
</tr>
<tr>
<td>2 Diagnose or monitor devices</td>
<td>II</td>
<td>II</td>
<td>III</td>
</tr>
<tr>
<td>3 Fluid delivery devices</td>
<td>II</td>
<td>II</td>
<td>III</td>
</tr>
<tr>
<td>4 Ionizing radiation devices</td>
<td>II</td>
<td>II</td>
<td>III</td>
</tr>
<tr>
<td>5 Implant devices</td>
<td>III</td>
<td>III</td>
<td>III</td>
</tr>
<tr>
<td>6 Other Active devices</td>
<td>II</td>
<td>II</td>
<td>III</td>
</tr>
</tbody>
</table>
Chinese STED
Required for all Classes of devices

- Risk Evaluation Report
- Product Specification
- Quality Control Testing Report
- Clinical Evaluation Report
- Summary of Manufacturing Process
- Draft Chinese Labelling
- Certificates and Declarations
## CFDA user fees

<table>
<thead>
<tr>
<th>Class</th>
<th>Domestic</th>
<th>Imported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class II</td>
<td>Initial registration</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>variation application</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Renewal (every 5 years)</td>
<td>–</td>
</tr>
<tr>
<td>Class III</td>
<td>Initial registration</td>
<td>153,600</td>
</tr>
<tr>
<td></td>
<td>variation application</td>
<td>50,400</td>
</tr>
<tr>
<td></td>
<td>Renewal (every 5 years)</td>
<td>40,800</td>
</tr>
<tr>
<td></td>
<td>High risk MD clinical trial approval</td>
<td>43,200</td>
</tr>
</tbody>
</table>
Clinical Trial Exemption List

**a) Demonstration of device is within the scope of the product in the Clinical Trial Exemption List.**

**b) Demonstration and Justification for equivalency of in-China predicate & comparison table with relevant supporting documents.**

<table>
<thead>
<tr>
<th>Comparison Items</th>
<th>In-China Predicate</th>
<th>Devices to be registered</th>
<th>Difference</th>
<th>Supporting documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Mechanism</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Working</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanism/Working Principle</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structure and composition</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturing materials or materials contact with body</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performance requirement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterilization/Disinfection method</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scope</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Instruction for Use</td>
<td></td>
<td></td>
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<tr>
<td>......</td>
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</tr>
</tbody>
</table>

Please note: The comparison item can be added depending on the devices.
Innovator Devices Fast Track

Single Contact Person to Manage Review

Advance Feedback from Test Centre

Classification category is decided in parallel with technical review

Special Review Team appointed by Office of Innovative Devices

Priority Processing

+ Design Controls and DHF
Fundamentals are here to stay

- Risk Based Classification
- Technical File
- Risk Management
- Design Controls
- Use of Standards
- (Essential Requirements)
3rd Party Assessment works

- Competence
- Confidence
- Objective accreditation criteria
New Technology

Refine classifications

Software devices

Expedited Pathways

• How many devices?
• but beware: the risks are less well understood
Common Ground

Streamline Lower Risk
Reduce duplication by harmonization

Strengthen Clinical Evidence for high risk
Use 3\textsuperscript{rd} parties – but make them strong

Harmony
With

Strength
Thank You