Classification Overview

FDA Small Business
Regulatory Education for Industry (REdI)
Silver Spring, MD
September 29, 2015

William M. Sutton
Deputy Director
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Learning Objectives

• Understand the history and terminology associated with device classification

• Identify and describe the three classes of devices

• Describe general controls and special controls

• Search the product classification database
Classification History

May 28, 1976 – Medical Device Amendments

• Section 201(h) of Federal Food, Drug & Cosmetic Act (FD&C Act)
  – Provides definition of a medical device

• FDA classification panels conducted initial classification of preamendments medical devices, i.e., Class I, II, III

• Initial classification completed in mid-1980s
A medical device is...

Section 201(h) of the FDCA defines a medical device as any product that does not achieve its purposes by chemical action or metabolization.

– As simple as a tongue depressor
– As complex as robotic surgery devices
What is a Preamendments Device?

• In commercial distribution before May 28, 1976

• Preamendments Class III devices require premarket approval (PMA) after FDA publishes regulation in the Federal Register (FR)

• Preamendments Class III devices may require premarket notification [510(k)], i.e., until FDA publishes a regulation
What is a Postamendments Device?

- First distributed commercially on or after May 28, 1976
- Automatically classified as Class III PMA, until FDA publishes a regulation
- Equivalent requirements to preamendments Class III devices, e.g., PMA or 510(k)
What is a Transitional Device?

- Regulated as new drug before May 28, 1976, e.g., intraocular lenses
- Any Class III transitional device now regulated as a PMA
- FDA application number begins with letter “N”
- Some have been downclassified to Class II
Is my Product a Device?

• If unable to determine if product meets the definition of a medical device, may seek FDA advice.

• Contact CDRH Office of Compliance by email at: DeviceDetermination@fda.hhs.gov

• Provide product description, draft labeling, and intended use

Device Advice Reference: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051521.htm
Classification “Terms”

• **Classified**
  – Formally classified by FDA classification panel or FDA,
  – Example: 21 CFR 880.2910 - Clinical electronic thermometer
  – Class II 510(k)

• **Un-classified**
  – Preamendments device pending formal classification with regulation, i.e., Class III 510(k)

• **Not Classified**
  – Postamendments device under application review
Device Classification

• Classification determines extent of regulatory control (risk-based)

• Regulatory Control increases from Class I to III

• Medical Specialty, e.g., cardiovascular

• Product Codes
Device Classification

• 1700 generic groups of devices
• Classified within 16 medical specialties
  – 21 CFR 862-892
  862 = Chemistry/Toxicology
  864 = Hematology/Pathology
  866 = Immunology/Microbiology
  868 = Anesthesiology
  870 = Cardiovascular
  872 = Dental
  874 = Ear, Nose and Throat
  876 = Gastro/Urology
  878 = General Plastic Surgery
  880 = General Hospital
  882 = Neurological
  884 = Obstetrical/Gynecological
  886 = Ophthalmic
  888 = Orthopedic
  890 = Physical Medicine
  892 = Radiology
Classification System
Risk Categorization

• Class I ~780 Low Risk
  – General Controls

• Class II ~800 Moderate Risk
  – General Controls and
  – Special Controls

• Class III ~120 High Risk
  – General Controls and
  – Premarket Approval
General Controls

• Adulteration/Misbranding
• Electronic Establishment Registration
• Electronic Device Listing
• Premarket Notification [510(k)]
• Quality Systems
• Labeling
• Medical Device Reporting (MDR)
Special Controls

• Guidelines (e.g., Glove Manual)
• Mandatory Performance Standard
• Recommendations or Other Actions
• Special Labeling

example: 21 CFR 882.5970, Cranial Orthosis
Class I – General Controls

• Level of Device Risk may be sufficiently managed by least amount of regulatory control

• Device Examples
  – adhesive bandage
  – I.V. stand
  – sunglasses
Class I – General Controls

Examples of General Controls

- Establishment Registration and Listing
- Quality System Regulations
- Labeling
- Premarket Notification [510(k)], unless exempt
Class II – Special Controls

- General controls alone are insufficient to assure safety and effectiveness

- Device Examples:
  - syringe, surgical mask, powered wheelchair

- Special Controls
  - special labeling
  - mandatory performance standard
  - guidelines
Class III – Premarket Approval (PMA)

- Insufficient information exist to assure S&E solely through general or special controls

- Device Examples
  - heart valves, implantable neuromuscular stimulator

- Class III is the most stringent category

- Support or sustain human life
Classification of New Devices

• “New” means that the device has not previously been classified

• By default, these devices are classified into Class III and require PMA approval, regardless of risk

• Regulatory burden may exceed what is necessary

• Potential Option: *de novo*
Classification of New Devices: \textit{de novo}

\textit{de novo} is a classification process:

- using a risk-based strategy
- for new, novel devices whose type has not previously been classified
- would be classified into Class III
- to classify into Class I or II
After *de novo* is granted

- **New Device is Legally Marketed**
  - Subject to post-market requirements applicable to that device and class (including general controls, special controls as applicable)

- **New Device Establishes New Classification**
  - The subject device is eligible to serve as a predicate for new medical devices, where appropriate [510(k) process]
  - New “device type” along with classification, regulation, class (either Class I or II), necessary controls and product code

- **FDA publishes order announcing new classification, controls**
Why is Classification Important to You?

- **How to classify your device?**
  - regulation number
  - classification database or device panel
  - product code
Product Classification Database

Advanced Search Options

Product Classification

This database includes:
- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

Search Database

Device

Review Panel

Submission Type

Implanted Device

Product Code

Regulation Number

Third Party Eligible

Device Class

Go to Quick Search

Clear Form

Search
## Syringe, Piston

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Syringe, Piston</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Description</td>
<td>Piston syringe.</td>
</tr>
<tr>
<td>Regulation Medical Specialty</td>
<td>General Hospital</td>
</tr>
<tr>
<td>Review Panel</td>
<td>General Hospital</td>
</tr>
<tr>
<td>Product Code</td>
<td>FUF</td>
</tr>
<tr>
<td>Premarket Review</td>
<td>Office of Device Evaluation (ODE) Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) General Hospital Devices Branch (GHDB)</td>
</tr>
<tr>
<td>Submission Type</td>
<td>510(k)</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>880.5660</td>
</tr>
<tr>
<td>Device Class</td>
<td>2</td>
</tr>
<tr>
<td>Total Product Life Cycle (TPLC)</td>
<td>TPLC Product Code Report</td>
</tr>
<tr>
<td>GMP Exempt?</td>
<td>No</td>
</tr>
<tr>
<td>Recognized Consensus Standards</td>
<td></td>
</tr>
<tr>
<td>- ISO 26825:2008-08-15 Anesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anesthesia - Colour, design and performance</td>
<td></td>
</tr>
<tr>
<td>- ISO 23306:2011-06-11 Sharpe injury protection - Requirements and test methods - Sharpe protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling</td>
<td></td>
</tr>
<tr>
<td>Guidance Document</td>
<td></td>
</tr>
<tr>
<td>- Guidance on the Content of Premarket Notification (510(k)) Submissions for Piston Syringes</td>
<td></td>
</tr>
<tr>
<td>Implanted Device?</td>
<td>No</td>
</tr>
<tr>
<td>Life-Sustain/Support Device?</td>
<td>No</td>
</tr>
<tr>
<td>Third Party Review</td>
<td>Eligible for Accredited Persons Program</td>
</tr>
<tr>
<td>Accredited Persons</td>
<td></td>
</tr>
<tr>
<td>- Bai Healthcare</td>
<td></td>
</tr>
<tr>
<td>- Center For Measurement Standards Of Industrial</td>
<td></td>
</tr>
<tr>
<td>- Deira Certification B.V</td>
<td></td>
</tr>
<tr>
<td>- Regulatory Technology Services, LLC</td>
<td></td>
</tr>
<tr>
<td>- Third Party Review Group, LLC</td>
<td></td>
</tr>
<tr>
<td>- Tur Sud America Inc.</td>
<td></td>
</tr>
</tbody>
</table>
21 CFR Parts 800 - 1299

a) Identification:
   – intended use
   – technological characteristics

b) Classification:
   – intended use/indications for use
   – technological characteristics
Regulations and Product Codes

Regulation Number: 880.5780

a)(1) Medical support stocking to prevent the pooling of blood in the legs.
   2) Class II and requires 510(k).
      • Product code DWL

b)(1) Medical support stocking for general medical purposes.
   2) Class I and is exempt from 510(k).
      • Product code FLL
How is My Device Classified?

• CDRH provides **non-binding**, informal advice on device classification and regulatory requirements.
• Section 513(g) submission to CDRH
• 60 day review cycle
• FY16 User Fee:
  – standard: $3529; small business: $1,765
• 513(g) guidance document:  
  [http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm209841.htm](http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm209841.htm)
Summary

- Terminology of device classification will assist in proper classification
- Correct classification of your device will outline the regulatory requirements
- Complying with general and special controls will assure timely review decisions and compliance
- Proper search of the product classification database will achieve successful results
Industry Education Resources

Three Resources

1. CDRH Learn – Multi-Media Industry Education
   - over 80 modules
   - videos, audio recordings, power point presentations, software-based “how to” modules
   - mobile-friendly: access CDRH Learn on your portable devices
   http://www.fda.gov/Training/CDRHLearn

2. Device Advice – Text-Based Education
   - comprehensive regulatory information on premarket and postmarket topics
   http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

3. Division of Industry and Consumer Education (DICE)
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2014 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm
Questions?

Please complete the session survey: surveymonkey.com/r/DEV-D1S2