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 – *General Controls*	~780	Low Risk
• Class II – *General Controls and* – *Special Controls*	~800	Moderate Risk
• Class III – *General Controls and* – *Premarket Approval*	~120	High Risk

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: *de novo*

***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?

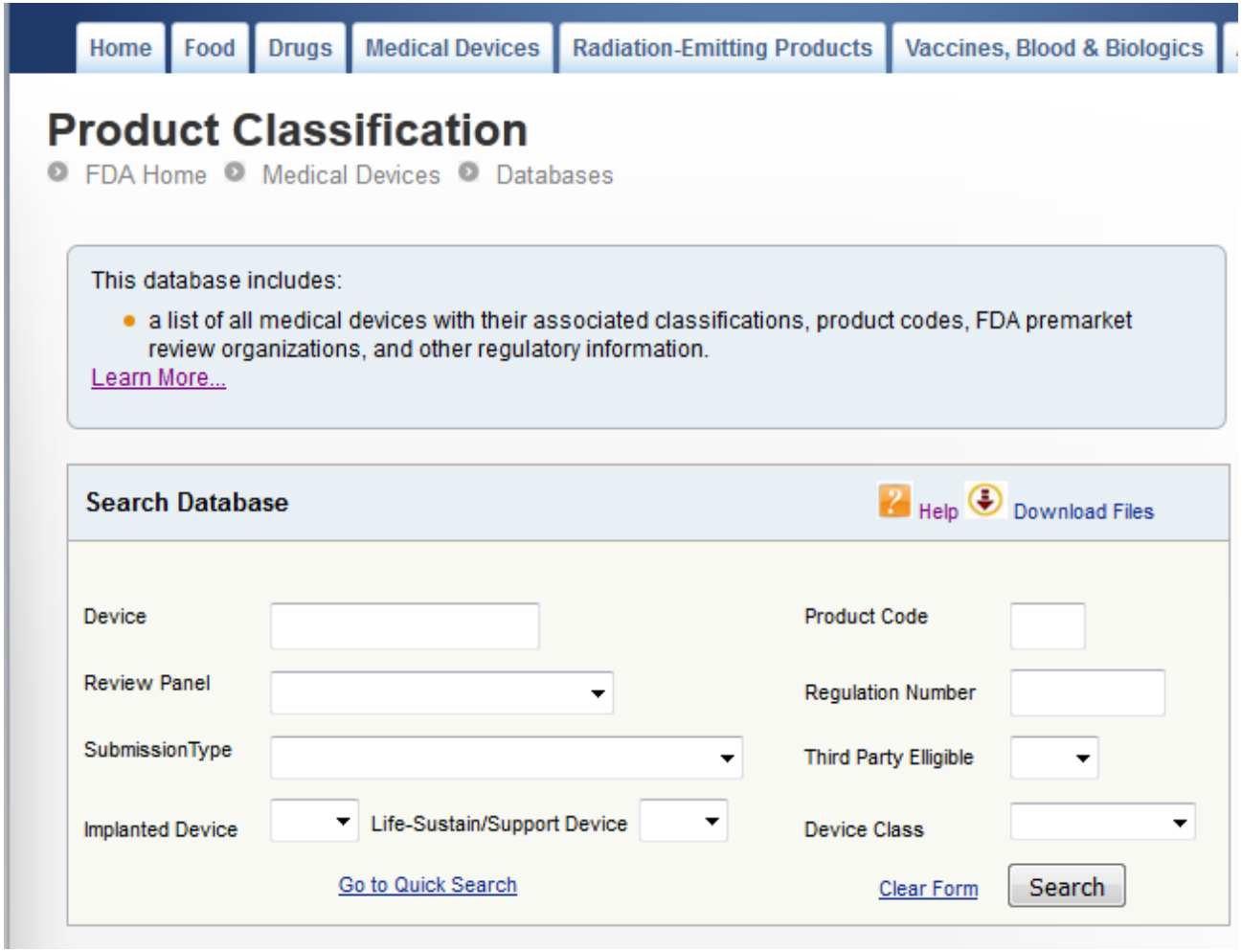
- **How to classify your device?**
  - regulation number
  - classification database or device panel
  - product code
  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

Product Classification Database

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm

Page Last Updated: 09/14/2015
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Advanced Search Options



Syringe, Piston

- Device Name
- Medical Specialty
- Product Code
- Premarket Review Office
- Submission Type

New Search | Back To Search Results

Device	Syringe, Piston
Regulation Description	Piston syringe.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	FMF
Premarket Review	Office of Device Evaluation (ODE) Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGRID) General Hospital Devices Branch (GHDB)
Submission Type	510(k)
Regulation Number	880.5860
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Recognized Consensus Standards

- ISO 26825 First edition 2008-08-15 Anaesthetic and respiratory equipment - User-applied labels for syringes containing drugs used during anaesthesia - Colours, design and performance
- ISO 7886-1 First edition 1993-10-01 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use [Including: Technical Corrigendum 1 (1995)]
- ISO 23908 First edition 2011-06-11 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Guidance Document

- Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes

Implanted Device?	No
Life-Sustain/Support Device?	No

Third Party Review

- Eligible for *Accredited Persons Program*

Accredited Persons

- Bsi Healthcare
- Center For Measurement Standards Of Industrial
- Dekra Certification B.v.
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc
- Tuv Sud America Inc.

- Regulation Number
- Device Class
- Recognized Consensus Standards
- Guidance Document

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

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