Device Registration and Listing: An Introduction – Part 1

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Device Registration and Listing Introduction

- **Part 1:**
  - **What, Why, and Who** is involved with registration and listing
- **Part 2:**
  - **How** to register and list

Learning Objectives

- Discuss background and key terms involved with device registration and listing
- Answer question: “Am I required to register and list?”
- Identify when you must register and list

Device Registration and Listing: Background, Definitions and Terms

What is Registration and Listing?

- **Registration:**
  - Informs FDA where an establishment is located
- **Listing:**
  - Informs FDA of activity that the establishment is performing on the medical device

Registration and Listing Definitions

- **Commercial Distribution:**
  - any distribution of a device intended for human use which is held or offered for sale

21 Code of Federal Regulations (CFR), 807.3(b)

Registration and Listing Definitions

- **Establishment:**
  - place of business
  - under one management at one general physical location
  - at which a device is manufactured, assembled, or otherwise processed

21 CFR 807.3(c)

Registration and Listing Terms

- **General Controls**
  - Regulatory requirements authorized by the Federal Food, Drug, and Cosmetic Act
  - Apply to all medical devices

www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls#gen

Regulatory Background

- **Medical device establishments are required to:**
  1. register their establishment
  2. list devices:
     - manufactured, prepared, propagated, compounded, assembled, or processed
     - at their establishment
- **Mandates use of electronic registration and listing system**
- **Requires payment of user fees**

Applicable Laws and Regulations

- Federal Food, Drug, and Cosmetic Act, Section 510 [1976]
- Food and Drug Administration Act (FDAAA) [2007]
- Food and Drug Administration Safety and Innovation Act (FDASIA) [2012]
- 21 Code of Federal Regulations (CFR) Part 807

  www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807

A Few Important Disclaimers

1. Registration does not, in any way, indicate approval or clearance of establishments or products per 21 CFR 807.39

2. FDA does not provide registration and listing "certificates"

Am I Required to Register and List?

Establishment Location

- **Domestic Establishment**
  - Physical location in the United States
  - Device marketed in the United States

- **Foreign Establishment**
  - Physical location outside the United States
  - Device marketed in the United States

Domestic Establishments Required to Register

Domestic Establishments Required to Register

- Manufacturer (including Kit Assembler)
  - of accessories or components
  - of export only devices
  - of custom devices
- Remanufacturer
- Specification developer
- Contract manufacturer and contract sterilizer
- Repackager
- Relabeler
- Reprocessor of single-use devices
- Complaint File establishment
- Initial importer

Domestic Establishments Required to Register

- **Manufacturer**
  - Makes by chemical, physical, biological, or other procedures
  - Any article that meets definition of a device
    - See 201(h) of the Federal Food, Drug, and Cosmetic Act
  - Include Kit Assembler

Domestic Establishments

- **Kit Assembler**
  - Places another establishment's finished device into a kit
  - Can't modify device or change intended use
  - Registers as either "manufacturer" or "contract manufacturer" based on activity

Domestic Establishments Required to Register

- **Manufacturer of Accessories or Components**
  - Packages or labels for commercial distribution for “health related purposes” to end user
- **Manufacturer of Export Only Devices**
  - Manufactures devices not sold in U.S.; solely for export to foreign countries
- **Manufacturer of Custom Devices**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/custom-device-exemption

Domestic Establishments Required to Register

- **Remanufacturer**
  - processes, conditions, renovates, repackages, restores, or does any other act to a finished device
  - that significantly changes its performance, safety specifications, or intended use

21 CFR 820.3(w)

Domestic Establishments Required to Register

- **Specification Developer**
  - Develops specifications for device distributed under establishment's own name
  - Performs no manufacturing
  - Uses contract manufacturer to make finished device

Domestic Establishments Required to Register

- **Contract Manufacturer and Contract Sterilizer**
  - Sterilizes, or otherwise makes a device for or on behalf of a specification developer or any other person
  - Arranges manufacturing for another establishment

Domestic Establishments Required to Register

- **Repackager**
  - Packages finished devices from bulk or
  - Repackages devices made by manufacturer into different containers
  - Excludes shipping containers
  - Can’t modify device or change intended use

Domestic Establishments Required to Register

- **Relabeler**
  - Changes content of labeling from original manufacturer
  - Distributes under establishment's own name
  - Doesn't include establishments that merely/only add their own name

Domestic Establishments Required to Register

- **Reprocessor of a Single-Use Device**
  - Modifies single-use device for more than one use
  - Previously used on a patient
  - Has responsibility for device

- **Complaint File Establishment**
  - Maintain complaint files according to 21 CFR 820.198

Domestic Establishments Required to Register

- **Initial Importer**
  - Further markets device from a foreign manufacturer
    - To person who makes final sale to user/consumer
  - Doesn't repackage or change container, wrapper, or labeling
  - 21 CFR 807.3(g)

Foreign Establishments Required to Register

Foreign Establishments Required to Register

- Manufacturer (including kit assemblers)
- Remanufacturer
- Specification developer
- Contract manufacturer and contract sterilizer
- Repackager
- Relabeler
- Reprocessor of single-use devices
- Complaint file establishment

➢ Similar to Domestic Establishments

Foreign Establishments Required to Register

- **Foreign Exporter**
  - Exports (or Offer for Export) to the United States
  - Device manufactured, prepared, propagated, compounded, or processed in a foreign country
  - Includes those originally manufactured in the United States
  - Must have an establishment address outside the United States

- **Private Label Distributor**
  - Exports device manufactured and owned by another party
  - Under own name and under a private label agreement

Who is Exempted from Registration and Listing?

Establishments Exempted from Registration

1. **Component Manufacturer**
   - Provides raw materials or components used in device manufacture or assembly
   - Provides only to finished device manufacturer
2. **Manufacturer of devices used solely for veterinary purposes**
   - FDA's Center for Veterinary Medicine (CVM) regulates veterinary use only devices
3. **Licensed Practitioner**
   - Manufactures or otherwise alter devices solely for use in own practice
   - May not distribute device to other practitioners

Establishments Exempted from Registration

4. **Installer**
   - By manufacturer's agent
   - By user

5. **Sponsor of devices under Investigational Device Exemption (IDE)**

6. **Domestic Distributor**

Establishments Exempted from Registration

7. Retail Establishment

- Provides device directly to end users
- Includes pharmacies and surgical supply outlets
- Note: If devices come from foreign establishments, ensure shipment is labeled as required

Establishments Exempted from Registration

8. **Manufacturer of research use only devices**
   - Labeled device as required and used solely for research, teaching or analysis
   - Not introduced into commercial distribution
   - Only applies to domestic establishment

Who Must Register, Summary

- **Who Must Register (Device Advice)**
  - Domestic or Foreign
  - Definitions
  - Regulatory citation

www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee

When Do I Register and List?

When to Register/List: It Depends!

- **Is this your first time (Initial)?**

OR

- **Is this not your first time (Annual)?**

Initial Registration and Listing

- **Domestic Establishment**
  - Within 30 days of placing device into commercial distribution
- **Foreign Establishment**
  - Prior to importing device to United States for first time*
- **Initial Importer**
  - Prior to importing device to United States for first time*
  - Only register; do not list device
  - Identify manufacturer of each imported device

*If not done, FDA work with Customs and Border Patrol to detain and hold shipment

Annual Registration and Listing

- **Must review registration information**
  - Complete annually, between October 1 – December 31 of each year
  - Submit any changes necessary
- **Must review listing information**
  - Review annually, between October 1 – December 31 of each year
  - Submit any changes necessary
- **May update information at any time**

Annual Registration and Listing

- **FDA recommends registration be deactivated**
  - If establishment discontinues marketing and distributing its device

Resources

Slide Number	Cited Resource	URL
7	21 CFR 807.3(b)	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-A/section-807.3#p-807.3(b)
8	21 CFR 807.3(c)	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-A/section-807.3#p-807.3(c)
9	General Controls (Device Advice)	www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls#gen
11	Code of Federal Regulations, Part 807	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807
17	201(h) of Food, Drug and Cosmetic Act	uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section321&num=0&edition=prelim

Resources

Slide Number	Cited Resource	URL
19	Custom Device Exemption (FDA Guidance)	www.fda.gov/regulatory-information/search-fda-guidance-documents/custom-device-exemption
20	21 CFR 820.3(w)	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820#p-820.3(w)
26	21 CFR 807.3(g)	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-A/section-807.3#p-807.3(g)
35	Who Must Register, List and Pay the Fee	www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee

Summary

- Registration and listing is a general control that applies to medical devices
- Different establishments types are required to register and list
- Registration and listing is required at time of initial distribution and, subsequently, on an annual basis

Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 200 modules - videos, webinars, presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information across the device total product life cycle: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: DICE@fda.hhs.gov
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4: 30 pm ET)

Your Call To Action

- Identify your type of establishment and determine whether you need to register and list
- If you must register and list, watch Part 2 of this Introduction on CDRH Learn


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