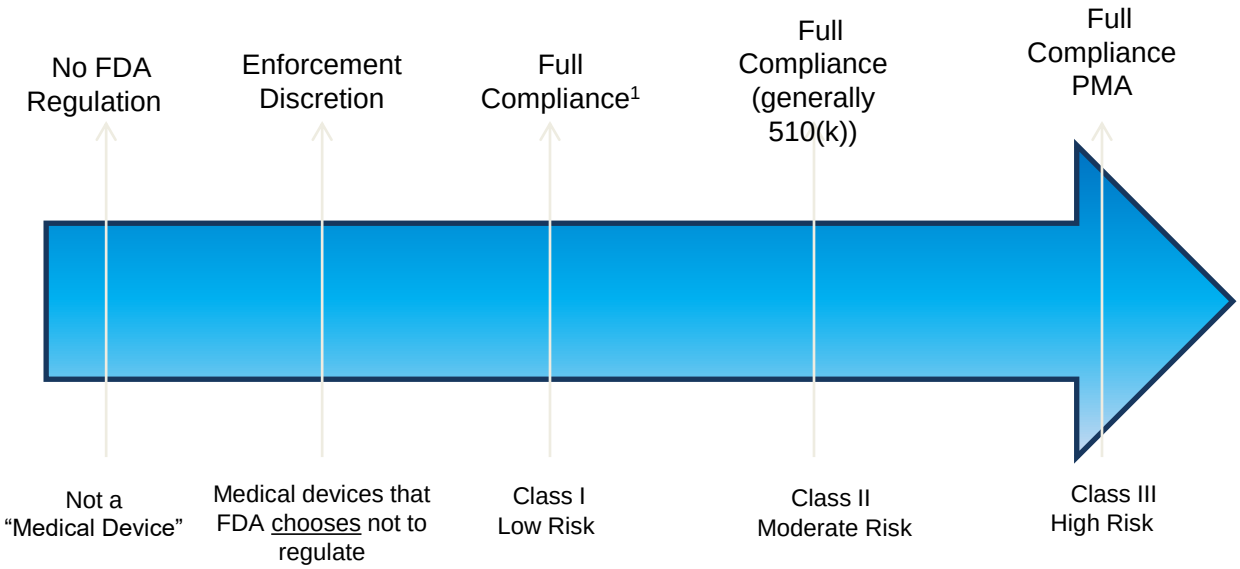
Medical Device Registration and Listing

November 16, 2021

FDLI

FDA Medical Device Regulatory Continuum



1. Unless otherwise exempt from certain requirements in the classification regulation (e.g., may be 510(k)-exempt).

Establishment Registration and Device Listing: Regulatory Requirements

- FDCA Section 510
- FDAAA
- FDASIA
- 21 C.F.R. Part 807
- Failure to register or list renders a device misbranded and is also a prohibited act

Overview

- Unless an exemption applies, an owner or operator of an establishment who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use must register and submit listing information for those devices in commercial distribution

Key Definitions

- **Establishment** - a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed
- **Owner or Operator** - the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment
- **Manufacture, preparation, propagation, compounding, assembly, or processing** - means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the FDCA.
  - These terms include the following activities:
    - (1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer
    - (2) Initial importation of devices manufactured in foreign establishments
    - (3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications

Key Definitions (cont'd)

- **Commercial Distribution** - any distribution of a device intended for human use which is held or offered for sale but does not include the following:
  - (1) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company
  - (2) Any distribution of a device intended for human use which has in effect an approved investigational device exemption (IDE)
  - (3) Any distribution of a device, before the effective date of 21 C.F.R. Part 812, that was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and that is classified into class III under section 513(f) of the FDCA
    - Provided that the device is intended solely for investigational use, and is not required to have an approved PMA
  - (4) For foreign establishments, the distribution of any device that is neither imported nor offered for import into the U.S.

Who Is Required to Register and List

- **Manufacturers**
  - Makes by chemical, physical, biological, or other procedures, any article that meets the FDCA definition of "device”
- **Remanufacturer**
  - Any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use
- **Repackagers**
  - Packages finished devices from bulk or repackages devices made by a manufacturer into different containers (excluding shipping containers)
- **Relabelers**
  - Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name
- **Contract Manufacturers**
  - Manufactures a finished device to another establishment's specifications
- **Contract Sterilizers**
  - Provides a sterilization service for another establishment's devices

Who Is Required to Register and List (cont'd)

- **Specification Developers**
  - Develops specifications for a device that is distributed under the establishment's own name but performs no manufacturing
  - Includes establishments that, in addition to developing specifications, also arrange for the manufacturing of devices labeled with another establishment's name by a contract manufacturer
- **Reprocessors of Single Use Devices**
  - Performs remanufacturing operations on a single use device
- **Complaint File Establishment**
  - Maintains complaint files as required under 21 C.F.R. 820.198
- **Initial Importers (Initial Distributors)**
  - Any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package
  - Required to register as a device establishment, but may fulfill listing obligations by submitting the name and address of the manufacturer (if did not develop specs, or repackage or relabel the devices)
- **Certain Component Manufacturers**

Who Is Required to Register and List (cont'd)

- Foreign Establishments
  - The registration and listing requirements also apply to foreign establishments that manufacture products for importation to the U.S.
  - "Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall register such establishment and list such devices"
  - Examples of Foreign Establishments Required to Register/List:
    - Manufacturers/Remanufacturers
    - Repackagers/Relabelers
    - Contract Manufacturers/Sterilizers
    - Specification Developers
    - Reprocessors of Single Use Devices
    - Complaint File Establishments
    - Foreign Exporters

Exemptions

- Examples of entities not subject to registration and listing under Part 807 (not exhaustive):
  - Wholesale distributors
  - Certain component manufacturers
    - Exempt – Manufacturers of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under Part 807
    - Not Exempt - Manufacturers of components or accessories that are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose
  - Manufacturers of general purpose articles not labeled for medical uses
  - Licensed practitioners who manufacture or otherwise alter devices solely for use in their practices
  - Pharmacies or other similar retail establishments making final delivery or sale to the ultimate user
  - Manufacturers of devices intended solely for use in research, teaching or analysis and that are not introduced into interstate commerce
  - Manufacturers of veterinary devices
  - Carriers by reason of their receipt, carriage, holding or delivery of devices in the usual course of business as carriers
  - Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer with a device or the benefits to be derived from the use of a device (e.g., a hearing aid dispenser, optician)

Domestic Establishments: Summary

Domestic establishments

Activity	Register	List	Pay Fee
Contract manufacturer (including contract packagers)	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Contract sterilizer	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Device being investigated under IDE	NO	NO 807.40(c)	NO
Domestic Distributor that does not import devices	NO 807.20(c)(3)	NO	NO
Any establishment located in a foreign trade zone involved with the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for commercial distribution in the United States	YES	YES	YES
Import agent, broker, and other parties who do not take first possession of a device imported into the United States	NO	NO	NO
Initial Importer	YES 807.40(a)	NO Identify manufacturers per 807.20(a)(5)	YES
Maintains complaint files as required under 21 CFR 820.198	YES	YES	YES
Manufacturer of accessories or components that are packaged or labeled for commercial distribution for health-related purposes to an end user	YES 807.20(a)(6)	YES 807.20(a)(6)	YES
Manufacturer of components, that are not otherwise classified as a finished device, that are distributed only to a finished device manufacturer	NO 807.65(a)	NO	NO
Manufacturer (including Kit Assemblers)	YES 807.20(a)	YES 807.20(a)	YES
Manufactures a custom device	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Refurbishers or remarketers of used devices already in commercial distribution in the United States.	NO	NO	NO
Relabeler or Repackager	YES 807.20(a)(3)	YES 807.20(a)(3)	YES
Remanufacturer	YES	YES	YES
Reprocessor of single use devices	YES 807.20	YES 807.20	YES
Specification Consultant Only	NO	NO	NO
Specification Developer	YES 807.20(a)(1)	YES 807.20(a)(1)	YES
U.S. Manufacturer of export only devices	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Wholesale distributor that is not a manufacturer or importer	NO	NO	NO

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

Foreign Establishments: Summary

Foreign Establishments

Activity	Register	List	Pay Fee
Contract Manufacturer (including contract packagers)	YES 807.40(a)	YES 807.40(a)	YES
Contract Sterilizer	YES 807.40(a)	YES 807.40(a)	YES
Custom Device Manufacturers	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
Device Being Investigated under IDE	NO 812.1 (a)	NO 812.1(a), 807.40(c)	NO
Foreign Exporter of devices located in a foreign country	YES 807.40 (a)	YES 807.40 (a)	YES
Foreign Manufacturers (including Kit Assemblers)	YES 807.40(a)	YES 807.40(a)	YES
Maintains complaint files as required under 21 CFR 820.198	YES	YES	YES
Manufacturer of accessories or components that are packaged or labeled for commercial distribution for health-related purposes to an end user	YES 807.20(a)(5)	YES 807.20(a)(5)	YES
Manufacturer of components that are distributed only to a finished device manufacturer	NO 807.65(a)	NO	NO
Relabeler or Repackager	YES 807.20(a)(3)	YES 807.20(a)(3)	YES
Remanufacturer	YES	YES	YES
Reprocessor of Single-use Device	YES 807.20(a)	YES 807.20(a)	YES
Specification Developer	YES	YES	YES

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

When to Register and List: Initial Registration

- Domestic Establishments
  - Within 30 days of putting a device into commercial distribution
- Foreign Establishments
  - Prior to exporting a device to the U.S. for the first time
- Initial Importers
  - Prior to importing a device to the U.S. for the first time

Registration Process

- Registration is through an electronic, web-based process
  - Unless FDA grants waiver from electronic registration
- Must first pay the annual registration fee
- Register establishment via the FDA Unified Registration and Listing Systems (FURLS)
  - Once a registrant pays the annual registration fee, they receive a Payment Identification Number (PIN) and a Payment Confirmation Number (PCN)
  - The PIN and PCN are needed to complete the FURLS registration

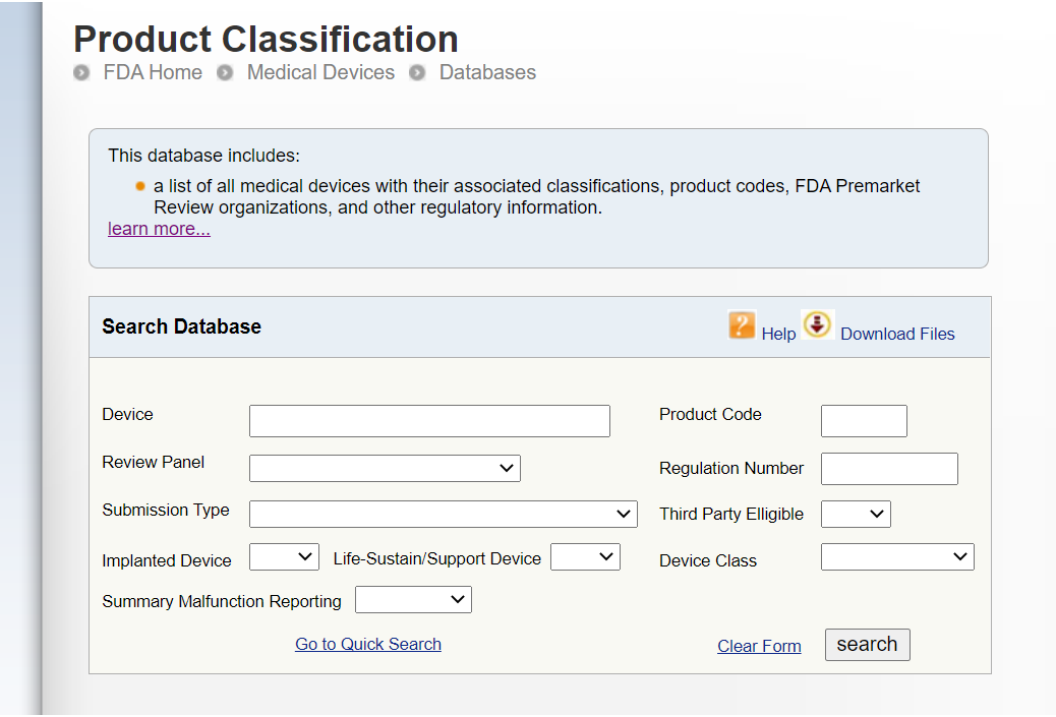
Information for Initial Registration

- Registration information required to be submitted includes:
  - the name and mailing address of the device establishment
  - the website address of the device establishment (if any)
  - the name, address, phone number, fax number, and email address of the owner or operator
  - the name, address, phone number, fax number, and email address of the establishment's official correspondent
  - all trade names used by the establishment

Information for Device Listing

- Information required for each device listed includes:
  - (1) The current registration number and name of each establishment under the ownership and control of the owner or operator where the device is manufactured, repackaged, relabeled, or otherwise processed, or where specifications are developed
  - (2) The product code for each device that is exempt from premarket notification and approval or which was in commercial distribution prior to May 28, 1976
  - (3) The proprietary or brand name(s) under which each device is marketed
  - (4) The FDA-assigned premarket submission number of the approved application, cleared premarket notification, granted de novo classification petition, or approved humanitarian device exemption (as applicable)
  - (5) Each activity or process that is conducted on or done to the device at each establishment
    - such as manufacturing, repacking, relabeling, developing specifications, remanufacturing, single-use device reprocessing, contract manufacturing, contract sterilizing, or manufacturing for export only
- Owners/operators may also be required to submit additional listing information upon specific request from FDA

Product Code Database



https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

Registration and Listing Numbers

- Registration Number
  - FDA will assign each device establishment a registration number after verifying the initial establishment registration information that has been submitted
  - The owner or operator of the establishment will also be assigned an identifying number
- Listing Number
  - Each successfully-created device listing generates a unique listing number
- Validation of registration and the assignment of a device listing number does not represent a determination by FDA as to the status of any device

Registration and Listing Updates

- Annual Registration
  - October 1 – December 31
  - Review and update all registration information and device listings, including delistings and adding any new listings
- Changes to listing information may also be made at other times
  - e.g., when a device is introduced into commercial distribution, when a change is made to a previously-listed device, or when a previously-listed device is removed from commercial distribution
- Certain changes must be reported within 30 days of the change:
  - Name and mailing address of the device establishment;
  - the Web site address of the device establishment;
  - the name, address, phone number, fax number, and email address of the owner or operator;
  - the name, address, phone number, fax number, and email address of the establishment's official correspondent;
  - all trade names used by the establishment

Device Listing Updates

- Although listing updates are only required once each year, FDA encourages all owner/operators to update their listing information on an ongoing basis as changes occur
- Examples of changes warranting an update to listing information include the following:
  - another device being introduced into commercial distribution
  - a change to a previously-listed device, such as where it is being manufactured,
  - a previously-listed device is removed from commercial distribution
  - commercial distribution of a previously-discontinued device is resumed

Official Correspondents

- Serves as point of contact with FDA on matters relating to the registration of a device establishment and device listings
- The official correspondent is responsible for:
  - Providing FDA with all required registration and listing information
  - Receiving all correspondence from FDA concerning registration and listing
  - Supplying, when requested by FDA, the names of all officers, directors, and partners
  - Receiving pertinent communications from FDA directed to and involving the owner/operator or the establishment
- The designation of an official correspondent does not affect the liability of the owner or operator of the establishment or of any other individual under the FDCA

United States Agent

- Foreign establishments must submit the name of a U.S. agent as part of registration
  - A U.S. agent means a person residing or maintaining a place of business in the U.S. whom a foreign establishment designates as its agent
  - Excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present
- U.S. Agent
  - Must reside in U.S.
  - Upon request from FDA, the U.S. agent assists FDA in communications with the foreign establishment, responds to questions concerning the foreign establishment's products that are imported or offered for import into the U.S., and assists FDA in scheduling inspections of the foreign establishment
- The U.S. agent can also serve as the official correspondent
- The foreign establishment or the U.S. agent must report changes in the U.S. agent's name, address, or phone number to FDA within 10-business days of the change

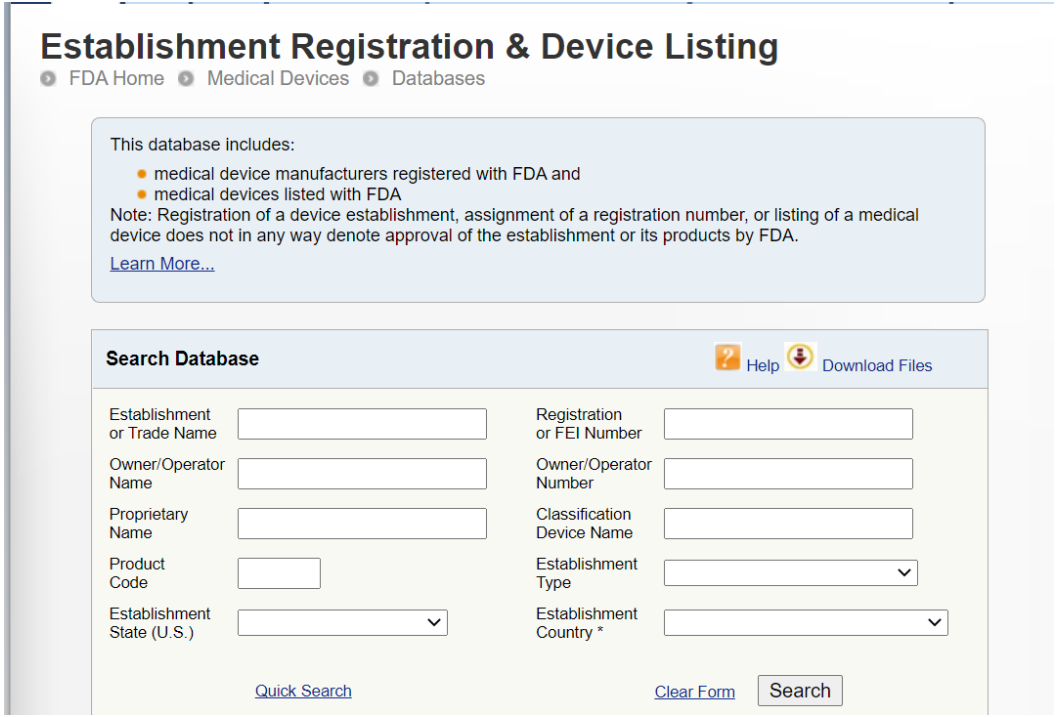
User Fees

- Any establishment required to register is also required to pay a user fee
- Congress has established a schedule of annual registration user fees

The annual registration user fee for fiscal year 2022 follows:

Year	FY 2022
Fee	$5,672

Establishment Registration and Listing Database



https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Examples of Ways FDA Uses Device Registration/Listing Information

- Identify establishments producing marketed medical devices
- Identify establishments producing a specific device when that device is in short supply or is needed for a national emergency
- Facilitate recall of devices marketed by owners or operators of device establishments
- Identify and catalogue marketed devices
- Administer FDA's postmarketing surveillance programs for devices
- Identify devices marketed in violation of the law
- Identify and control devices imported or offered for import into the U.S. from foreign establishments
- Schedule and plan inspections of registered establishments
- Generate accurate estimates of the number of businesses that are affected by FDA rulemaking activities

State Law Requirements

- Most states have laws requiring that device manufacturers and/or distributors register or hold a license
- Laws vary by state

Questions?