Registration and Listing

Lisa Marie King
Consumer Safety Officer
Imports and Registration & Listing Team (IRLT)
Division 2 – Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
April 26, 2022
Lisam.king@fda.hhs.gov

Presentation Outline

- Regulatory Authority
- 21 CFR 807 Revised Regulation Changes
- Who is required to register and list
- When to register and list
- Electronic Registration and Listing
- What info is needed to R&L
- Sources of R&L Info
- Firms R&L Contact Info

Regulatory Authority

- **Section 510 of Food, Drug and Cosmetic Act (FD&C Act)**
  - Enacted in 1976, since amended
  - Requires medical device establishments to register and list
- **Food and Drug Administration Amendments Act (FDAAA)**
  - Enacted in September 2007
  - Mandated the use of an electronic registration and listing system
  - Introduced user fees for many establishment types

Regulatory Authority

- **Food and Drug Administration Safety and Innovation Act (FDASIA)**
  - Enacted July 2012
  - Expanded user fee to all establishment types

- **21 CFR Part 807, revised**
  - Published August 2, 2012
  - Explains specific regulatory registration and listing requirements
  - Revised regulations effective October 1, 2012 for Fiscal Year 2013

Revised Regulation Changes

- All establishments must pay the annual registration user fee
- Proprietary Names are required
  - User can upload from Excel spreadsheet
  - Names that would identify relationships can be marked confidential
- Initial importers must identify manufacturers of products imported
- Foreign establishments importing or offering a device a device for import must identify all importers “known to them”
  - Users can upload from Excel spreadsheet

Revised Regulation Changes

- All contract manufacturers and sterilizers required to register and list
- Product must be listed by manufacturer or specification developer before contract manufacturer or sterilizer can list
- Complaint handler establishment type added

- When combination products are listed, must identify the type of combination (device/drug, device/biologic, etc.)

Who is Required to Register and List

U.S. Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | FDA Voice Blog
SEARCH
Most Popular Searches

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Medical Devices

Home › Medical Devices › Device Advice: Comprehensive Regulatory Assistance › How to Market Your Device

- Device Advice: Comprehensive Regulatory Assistance
- How to Market Your Device
- Medical Device Registration and Listing
- Important Reminders about Registration and Listing
- Access Electronic Registration
- ▶ Who Must Register, List and Pay the Fee
- When to Register and List
- How to Register and List
- Payment Process
- U.S. Agents
- Frequently Asked Questions about the New Device Registration and Listing Requirements
- Documents
- Search Registration and Listing
- Contact Us

Who Must Register, List and Pay the Fee

Effective FY2013 (October 1, 2012) the requirements for medical device establishment registration and listing will have changed. Please see Medical Device Establishment Registration and Listing - Notice of Changes for FY 2013 for important information.

Please contact reglist@cdrh.fda.gov for further information.

Establishments that are involved in the production and distribution of medical devices intended for commercial distribution in the United States (U.S.) are required to register annually with the FDA. Most establishments that are required to register are also required to list the devices and the activities performed on those devices at that establishment.

The following charts detail the requirements for registration and listing based on the type of activity performed at that establishment. The chart also includes a column showing which types of activities require payment of the establishment registration fee. See the Payment Process page for additional details.

- Domestic establishments
- Foreign establishments
- Definitions of establishment types

Domestic establishments

Activity	Register	List	Pay Fee
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
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
U.S. Manufacturer of export only devices	YES 807.20(a)(2)	YES 807.20(a)(2)	YES

Reference:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm

When to Register and List

- **Domestic Establishments:**
  - Within **30 days** after entering into activity

- **Initial Importers:**
  - Prior to importing a medical device into the U.S.
  - Only required to register; they do no list device
  - Must identify the name and address of the manufacturer of each device imported.

- **Foreign Establishments:**
  - Prior to devices being imported or offered for import into the U.S.
  - Must identify anyone known to them who imports their product or offers their product for import
  - Identify a U.S. Agent

Foreign Establishment Requirements
U.S. Agent

All foreign establishments must:

- Appoint a **single** U.S. agent and identify the agent separately to each Center
- U.S. agent must reside or have a physical place of business in the United States - no Post Office boxes or mail drops allowed
- U.S. agent is not required to register

Device Listing Requirements

- All establishments that are required to register also required to list with the exception of initial importers
- All exempt devices fall under same product code have only one listing (not each model, catalog number, brand name)
- All non-exempt devices must have a separate listing for each 510(k), PMA, NDA, HDE or PDP number
- Identify all proprietary or brand names under which the product is marketed in the U.S.
- Identify if a device is a combination product (device/drug, device/biologic)

Electronic Registration and Listing

- FDA Unified Registration and Listing System (FURLS) Device Registration and Listing Module (DRLM) launched on October 1, 2007
  - Web-based entry of R&L information
  - All establishments must register and list electronically (on-line) unless waiver granted
  - Congress establishes the schedule of annual registration user fees
  - No reduction in fee for small businesses or any other groups

Electronic Registration and Listing

- Annual registration October 1 – December 31st of each calendar year

- Review Registration Information and make any updates
  - Are Owner/Operator, Official Correspondent and U.S. Agent email addresses, correct?

- Review listings and make any updates
  - Do you need to update proprietary names?
  - Do you need to update the lists of manufacturers or initial importers/importers?

Electronic R&L (cont'd):

Domestic Establishments	Foreign Establishments	Initial Importers
1. Pay the Annual Registration User Fee via the Device Facility User Fee (DFUF) website.	1. Pay the Annual Registration User Fee via the Device Facility User Fee (DFUF) website.	1. Pay the Annual Registration User Fee via the Device Facility User Fee (DFUF) website.
2. Register the establishment in the FURLS/DRLM.	2. Register the establishment in FURLS/DRLM.	2. Register the establishment in FURLS/DRLM. 3. Do not list.
3. List the device(s) and identify all proprietary names. Note: May mark names as confidential.	3. List the device(s) and identify all proprietary names. Note: May mark names as confidential.	4. Identify manufacturer for each device imported.
	4. Identify initial importers or importers	
	5. Identify U.S. Agent	

General Problems/Issues

- Firms cannot remember their account id, username or passwords for systems
- Firms attempt to register and list before paying
- Firms pay but do not complete annual registration
- Firms wait to register until end of calendar year
- Firms allow registration to lapse and devices get detained

Device Facility User Fee (DFUF) Website

- CDRH Learn Module on how to pay the annual registration user fee can be found at https://www.accessdata.fda.gov/cdrh_docs/presentations/AnnualFee/story_html5.html

- For questions and guidance regarding this website, please reach out to the User Fee Helpdesk by phone at 301-796-7200 or by e-mail at: userfees@fda.gov

- Once you have received your Payment Identification (PIN) and Payment Confirmation Number (PCN) you can proceed to complete the registration process in FURLS.

What info is needed to register?

If completing your annual registration, you will need:

- Username and Password to pay annual registration user fee via DFUF website
- Account id and Password to access FURLS/DRLM to complete your annual registration
- Payment Identification Number (PIN)/Payment Confirmation Number (PCN)

What info is needed to register?

If completing an initial registering or registering for the first time, the official correspondent or owner/operator contact will need to:

- Create an account to pay the annual registration user fee via DFUF website
- Pay the annual registration user fee and obtain your PIN/PCN
- Create an account to register your establishment via FURLS/DRLM

What info is needed to register?

- The owner or operator's business name, address and contact information (including email address)
- The name, address and contact information (including email address) of the person who will be your official correspondent
  - Can be the same as your owner or operator contact person
- Foreign establishments only
  - The name, address and contact information (including email address) for the US agent

What info is needed to register?

- The name and address of the establishment you are registering
- For devices that are exempt from premarket clearance or approval:
  - Product code for the device
  - The activity (manufacture, relabel, etc.) being performed on the device
  - The proprietary or brand names that the device is marketed under

What info is needed to register?

- For devices that require FDA clearance or approval:
  - The submission number from your clearance or approval letter (K123456, P123456, N12345, etc.)
  - The product codes will be pulled premarket submission record
  - The activity (manufacture, relabel, etc.) being performed on the device
  - The proprietary or brand names that the device is marketed under
- Foreign establishments only -
  - The registration number of initial importer
  - Name and address of any non-registered importer

What info is needed to register?

- Initial importers must identify the manufacturer of the product(s) they import
  - Listing number
  - Registration number
  - Name or address for establishment
- If you are registered as a specification developer for the product that you import, you do not need to identify yourself as an initial importer for that product.

Registration and Listing Home Page -

Device Registration and Listing

FDA does not issue Registration Certificates to medical device establishments. FDA does not certify registration and listing information for firms that have registered and listed. Registration and Listing does not denote approval or clearance of a firm or their devices.

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration (Title 21 CFR Part 807).

Congress has authorized FDA to collect an annual establishment registration fee for device establishments. A detailed list of the types of device establishments that are required to register and pay the fee can be found at "Who Must Register, List and Pay the Fee". The establishment registration fee is not eligible for a reduced small business fee.

The annual registration user fee for fiscal year 2021 follows:

Content current as of:
10/01/2020

Regulated Product(s)
Medical Devices

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm

Sources of R&L Information

1. Registration and Listing and FURLS Information
2. Establishment Registration (part of Device Advice)
3. Medical Device Listing (part of Device Advice)
4. Releasable Establishment Registration and Device Listing Files for download
5. Product Code Classification Database

Sources of R&L Information

7. CDRH Learn
   - Overview of Registration and Listing Requirements
   - Paying the annual registration user fee via the Device Facility User Fee (DFUF) website
   - Device Registration and Listing Module (DRLM) for Annual Registration
   - FURLS Device Registration and Listing Module for Initial Registration

8. Device Facility User Fee (DFUF) Website

Firms R&L Contact Info

- E-mail is best way to contact us:
  - Assistance with Annual Registration Process or FURLS/DRLM: reglist@cdrh.fda.gov
  - Assistance with policy questions and import detention issues: device.reg@fda.hhs.gov

- Phone number:
  - 301-796-7400
    - Option 1 for help with FURLS/DRLM
    - Option 2 for help with detention or policy issues

IRLT Contacts

- Deniz B. Mackey, Assistant Director
- Lisa Marie King, Consumer Safety Officer
- Edward Nyack, Senior Program Analyst
- Daniel LaShoto, Biomedical Engineer

Questions?