This information should not be considered to represent advice or guidance on behalf of the U.S. Department of Health and Human Services or any agency or office thereof.

FDA CDRH Registration and Listing Requirements

Context

Whether or not a premarket application or approval is required, an innovator seeking to market a medical device in the U.S. is required to register and list the device with the FDA as well as pay any applicable fees. This requirement generally applies to all innovators (in this context often referred to as establishments) developing or manufacturing a Class I, II, or III device. If your device requires a premarket application and/or approval from FDA, you must wait for your device to be cleared or approved before registering it. After approval, the innovator must complete the registration and listing process. If your device does not require a premarket application—either because of its classification or if it is exempt—then registering and listing the device may be the innovator's first and only required interaction with FDA.

Innovators must meet all registration and listing requirements before marketing and distributing a device in the U.S.

Who Needs to Register?

NIH innovators may be engaged in a wide range of medical device development and manufacturing activities. FDA keeps an expansive list of activities that require an innovator to register, list, and pay fees. Below is a subset of the activities that NIH innovators are most involved in and their registration requirements.

Type of Activity Innovator Intends to be Involved in:	Activity Definition	Required to Register, List, and Pay Fees
Device being investigated under an Investigational Device Exemption (IDE)	Any type of activity involved in manufacturing a device being investigated under an IDE.	**NO**

Type of Activity Innovator Intends to be Involved in:	Activity Definition	Required to Register, List, and Pay Fees
Manufacturer of components, that are not otherwise classified as a finished device, that are distributed only to a finished device manufacturer	Makes components of devices that independently are not considered medical devices.	**NO**
Specification consultant only	Develops specifications for a device that is distributed under another establishment's name and performs no manufacturing of their own.	**NO**
Manufacturer (including Kit Assemblers)	Makes by chemical, physical, biological, or other procedures, any product that meets the definition of a medical device.	**YES**
Manufacturer of a custom device	Makes by chemical, physical, biological, or other procedures, any custom product that meets the definition of a medical device.	**YES**
Manufacturer of accessories or components that are packaged or labeled for commercial distribution for health-related purposes to an end user	Makes by chemical, physical, biological, or other procedures, any product or component that independently meets the definition of a medical device.	**YES**
Contract manufacturer (including contract packagers)	Manufactures any product that meets the definition of a finished medical device to another establishment's specifications.	**YES**
Specification developer	Develops specifications for a medical device that is distributed under the establishment's own name but performs no manufacturing. This 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.	**YES**

Type of Activity Innovator Intends to be Involved in:	Activity Definition	Required to Register, List, and Pay Fees
Maintains complaint files as required under 21 CFR 820.198	Manufacturer that is required to maintain complaint files as part of quality system regulation.	**YES**
Remanufacturer	Any establishment 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.	**YES**
Reprocessor of single use devices	Any establishment that performs remanufacturing operations on a single use device.	**YES**
Any establishment located in a foreign country involved with the manufacturing, preparation, propagation, compounding, assembly, or processing of a device intended for commercial distribution in the U.S.	Exports or offers for export to the U.S., a device manufactured, prepared, propagated, compounded, or processed in a foreign country, including devices originally manufactured in the U.S. A foreign exporter must have an establishment address outside the U.S.	**YES**
U.S. manufacturer of export only devices	Any establishment that manufactures medical devices that are not sold in the U.S. but are manufactured in the U.S. solely for export to foreign countries.	**YES**

Registering with FDA

The registration of a medical device establishment is a multi-step process. The registration is not considered complete until you:

(1) Pay the annual registration user fee
(2) Submit the registration and listing information electronically
(3) Receive email confirmation from FDA that all requirements have been met

Paying the Annual Registration Fee

All establishments required to register must **first** pay the user fee through the User Fee Payment system. Once the payment is received, you will receive confirmation numbers for the payment that will contain the Payment Identification Number (PIN) and the Payment Confirmation Number (PCN). At this point, you can proceed to the FDA User Registration Listing and Systems (FURLS)/FDA Industry System (FIS) website to complete your registration and listing requirements.

Registering your Facility

If you have never previously registered a device establishment, you will need to first create an appropriate type of FURLS account. The two types of FURLS accounts are:

- Owner/operator –The corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registered establishment. As such, the owner/operator is responsible for creating sub-accounts for any official correspondents he/she identifies.
- Official correspondent – The person designated by the owner/operator of an establishment responsible for the annual registration of the establishment and the device listing. The official correspondent also receives correspondence from the FDA involving the owner/operator and any of the firm's establishments. The official correspondent is responsible for the registration and listing information for each establishment to which he/she is assigned.

Once you have set up a FURLS account ID and password, select the Device Registration and Listing Module (DRLM) option followed by the "Register a Medical Device Facility" link. Since you do not have any existing registration, the owner/operator number or registration number fields can be left blank and "No existing registration or OO number" should be selected.

Initial registration of your establishment must be submitted within 30 days *before* marketing a device for commercial distribution. It can be submitted earlier.

After the initial registration, you are required to complete Annual Registration for as long as you continue to market the device. To complete the annual registration for an already registered establishment, log on with your existing FURLS account ID and password. It is important not to create a new account if an establishment already has a FURLS account ID. Creating a new account will prevent you from accessing your current registration. From your FURLS account, select the "Annual Registration" link from the DRLM main menu. Then select the Annual Registration link and complete this process for your establishment to be considered registered for the current fiscal year. Selecting this Annual Registration link will also allow you to update your registration and listing information. Review the registration and listing information for your establishment and make updates, if needed.

Annual registration and listing information must be submitted each year between October 1 and December 31.

General Tips

- While researching, conducting non-clinical testing, and pivotal or clinical trials of a medical device under development it is not necessary to register your organization.
- Regardless of premarket application and approval requirements, any innovator manufacturing, marketing, or distributing a product that meets the definition of a medical device is required to complete the registration and listing as well as pay the associated fees, annually.
    - Note that if multiple establishments are involved in the manufacturing of your device each establishment that is engaged in a qualifying activity may need to complete its own registration and listing with the FDA. For example, if you develop and market a medical device but use a contract manufacturer to manufacturer the device itself, then both you and the contract manufacturer may be required to each pay your own fees and complete a separate registration and listing.

Regulatory Resources

- Guidance documents and FDA resources
    - How to Determine If Your Product Is a Medical Device – device determination steps
    - Device Registration and Listing – annual registration information
    - Who Must Register, List and Pay the Fee – requirements for registration based on the type of activity performed
    - Payment Process – fee payment information
    - How to Register and List – general information
    - User Fee Payment System
    - Online Account Administration (OAA)
- NIH network
    - Work with program officers and obtain regulatory feedback within NIH
    - NIH awardees can request a meeting with the NIH Small Business Education and Entrepreneurial Development (SEED) Innovator Support Team to ask questions about this process.

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