



Establishment Registration & Device Listing with FDA



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What does it mean?

Establishments that are involved in the production and distribution of medical devices intended for commercial distribution in the United States (U.S.), including those that are imported for export only, are required to register annually with the FDA.

Most establishments that are required to register are also required to list their devices and the activities performed on those devices at that establishment (Title 21 CFR Part 807)



FDA employs an electronic system for the registration of all facilities 'FURLS' (FDA's Unified Registration and Listing System). Manufacturers, processors and distributors must list all devices produced or processed at each facility. Initial importers (facilities that take first title to a device imported into the United States) must list all manufacturers of the devices they are importing from.

What is the Establishment Registration Process?

To register a medical device establishment with FDA is a two-step process:

Step-1: Payment of the annual registration user fee: The establishment must pay the annual registration fee electronically at the Device Facility User Fee (DFUF) website. Notification of payment confirmation and Payment Identification Number (PIN) is received when payment is made on the DFUF site. Payment Confirmation Number (PCN) is received by email once the payment has cleared. Once confirmation is received, facility registration process can be initiated.

Step-2: Submission of the registration and listing information electronically: Registration and listing information is submitted by using FDA's Unified Registration and Listing System (FURLS)/ Device Registration and Listing Module (DRLM). An account id and password is provided for every owner/operator to access and use FURLS. The official correspondent is responsible for the registration and listing information for each establishment, and they operate through a designated account.

After establishment registration, you will receive an email notification from FDA that all the requirements have been met.

Who should Register and List?

Activity	Register	List	Pay Fee	Regulation
Contract Manufacturer (including contract packagers)	Yes	Yes	Yes	807.40(a)
Contract Sterilizer	Yes	Yes	Yes	807.40(a)
Custom Device Manufacturers	Yes	Yes	Yes	807.20(a)(2)
Foreign Exporter of devices located in a foreign country	Yes	Yes	Yes	807.40 (a)
Foreign Manufacturers (including Kit Assemblers)	Yes	Yes	Yes	807.40(a)
Manufacturer of accessories or components that are packaged or labeled for commercial distribution for health-related purposes	Yes	Yes	Yes	807.20(a)(5)
Manufacturer of components that are distributed only to a finished device manufacturer	No 807.65(a)	No	No	807.65(a)
Relabeler or Repackager	Yes	Yes	Yes	807.20(a)(3)
Reprocessor of Single-use Device	Yes	Yes	Yes	807.20(a)
Specification Developer	Yes	Yes		Yes

When to Register and List?

All companies are required to register their establishments and list their medical devices after receiving product approval/clearance. Initial registration has to be followed up every year, along with payment of an annual fee. Manufacturers can access the electronic system to make changes to the information anytime.

1. Initial Registration

Establishment registration and products listing information must occur within 30 days of an establishment beginning an activity or putting a device into commercial distribution. Foreign establishments must register before exporting products to the United States. For devices that require FDA approval before commercialization, companies have to wait until their products get approved (510(k) or PMA) to be able to proceed with establishment registration and device listing.

2. Annual Registration

Establishment registration and products' listing must be submitted to FDA each year between October 1 and December 31, even if no changes have occurred.



Establishment registrations are based on FDA's fiscal year which runs from October 1 to September 30. FDA will continue to consider an establishment's registration active through the end of each calendar year.

3. Updating Registration and Listing information

All companies can access FURLS at any time throughout the year to update changes to their registration and listing information as those changes occur. Examples of changes to listings include:

1. Another device being introduced into commercial distribution,
2. A change to a previously listed device, such as where it is being manufactured,
3. A previously-listed device is removed from commercial distribution or commercial distribution is resumed.

Definitions of Establishment Activities

Contract Manufacturer

Manufactures a finished device to another establishment's specifications.

Contract Sterilizer

Provides a sterilization service for another establishment's devices

Foreign Exporter

Exports or offers for export to the United States (U.S.), a device manufactured, prepared, propagated, compounded, or processed in a foreign country, including devices originally manufactured in the United States. A foreign exporter must have an establishment address outside the U.S.

Initial Importer

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. The initial importer must have a physical address in the United States staffed by individuals responsible for ensuring the compliance of imported devices with all applicable FDA laws and regulations.

Manufacturer

Makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" in Section 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act

Repackager

Packages finished devices from bulk or repackages devices made by a manufacturer into different containers (excluding

Relabeler

Changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling but merely add their own name.

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.

Specification Developer

Develops specifications for a 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.

Need help with classification and regulatory pathway for your medical device in the US?

Global Regulatory Partners helps in developing the optimum regulatory strategy for your medical devices. To learn more about how we can serve as an U.S. agent for your medical device/IVD company, check out our white paper on this subject or Contact Us today!

U.S. Agent for Foreign Companies

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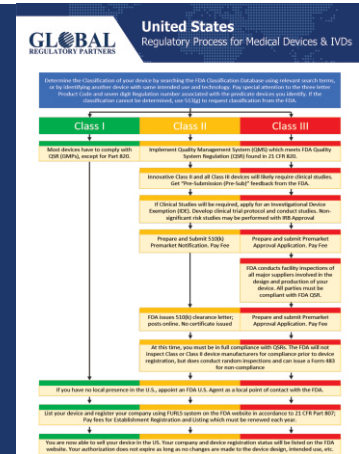
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Need help with medical device & IVD registration in the US?

Global Regulatory Partners helps medical devices companies register their products with the FDA and access U.S. market by providing the following services:

- Medical Device Classification
- Pre-Submission meetings with the FDA
- Medical Device Registration
- FDA 21 CFR Part 820 - Quality Management System

For detailed information, check out our white paper on Medical Device Registration Process in US today!



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