Device Registration and Listing

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).

Establishments	Register/ Pay Fee	Device Listing
Initial Importer	YES	NO
Contract Manufacturer (including contract packagers)	YES	YES
Contract Sterilizer	YES	YES
Custom Device Manufacturers	YES	YES
Foreign Exporter of devices located in a foreign country	YES	YES
Foreign Manufacturers (including Kit Assemblers)	YES	YES
Maintains complaint files as required under 21 CFR 820.198	YES	YES
Manufacturer of accessories or components that are packaged or labeled for commercial distribution for health-related purposes to an end user	YES	YES
Relabeler or Repackager	YES	YES
Remanufacturer	YES	YES
Reprocessor of Single-use Device	YES	YES
Specification Developer	YES	YES
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
U.S. Manufacturer of export only devices	YES	YES

U.S. Agents

Any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device imported into the United States must identify a United States agent (U.S. agent) for that establishment.

The foreign establishment may also designate its U.S. agent as its official correspondent.

The U.S. agent must either reside in the U.S. or maintain a place of business in the U.S. They must be available to answer the phone or have an employee available to answer the phone during normal business hours.

The U.S. agent cannot use a post office box as an address or use just an answering service.

Misbranding (Establishment and Listing Violations)

Section **502** of the Federal Food, Drug and Cosmetic Act (FFDCA) contains provisions on **misbranding**. A device is considered to be "**misbranding**" if the establishment is **NOT** registered with FDA as required by Section 510 of the FFDCA and has **NOT** listed the device as required by Section **510(j)** of the FFDCA or obtained applicable premarket notification clearance as required by Section 510(k) of the FFDCA.

FDA Judicial actions

When a firm violates the Federal Food, Drug and Cosmetic Act (FFDCA), the U.S. FDA can perform judicial enforcement actions. E.g. *seizure, injunction, civil money penalties for radiation-emitting products, and criminal prosecution.*

We can help you

Focus 42 LLC can performs all services required by the U.S. Agent, and can register your facility and handle your product listings with the FDA. Click here to get your free proposal.