# Device Registration

| Activity | Domestic | Foreign |
|---|---|---|
| **Manufacture**r (including Kit Assemblers) | YES<br>807.20(a) | YES<br>807.40(a) |
| Manufactures a custom device | YES<br>807.20(a)(2) | YES<br>807.20(a)(2) |
| **Manufacturer** of accessories or components that are packaged or labeled for commercial distribution for health-related purposes to an end user | YES<br>807.20(a)(6) | YES<br>807.20(a)(6) |
| **Manufacturer** of components that are distributed only to a finished device manufacturer | NO<br>807.65(a) | NO<br>807.65(a) |
| **U.S. Manufacturer of export only devices** | YES<br>807.20(a) | -- |
| **Relabeler or Repackager** | YES<br>807.20(a)(3) | YES<br>807.20(a)(3) |
| **Contract manufacturer (including contract packagers)** | YES<br>807.20(a)(2) | YES<br>807.20(a)(2) |
| **Contract sterilizer** | YES<br>807.20(a)(2) | YES<br>807.20(a)(2) |
| Domestic Distributor | NO<br>807.20(c)(3) | -- |
| **Specification Developer** | YES<br>807.20(a)(1) | YES<br>807.20(a)(1) |
| Specification Consultant Only | NO | NO |
| **Foreign Exporter** of devices located in a foreign country | -- | YES<br>807.40(a) |
| **Initial Importer** | YES<br>807.40(a) | -- |
| Import agent, broker, and other parties who do not take first possession of a device imported into the United States | NO | -- |
| Device being investigated under IDE | NO<br>812.1(a) | NO<br>812.1(a) |
| **Reprocessor** of single use devices | YES<br>807.20(a)(4) | YES<br>807.20(a)(4) |
| **Remanufacturer** | YES | YES |
| Maintains complaint files as required under 21 CFR 820.198 | YES | YES |
| Establishments located in foreign trade zone | YES | -- |
| Refurbishers | NO | -- |

# 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** - Takes first title to devices imported into the U.S. An Initial Importer must have a U.S. address.

**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 shipping containers).

**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.

**Reprocessor** of Single Use Device - Performs remanufacturing operations on a single use device.

**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.

**U. S. manufacturer of export only devices** - Manufactures medical devices that are not sold in the U.S. and are manufactured solely for export to foreign countries.