Initial Importer

Note: References to the pages on the FDA website use the UCM number only to avoid long URLs.

An *Initial Importer* is an 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. [Source: UCM053165]

Foreign Manufacturer
In this situation, a foreign manufacturer makes the device. The initial importer brings it into the US. The analysis starts with the requirements for the foreign manufacturer.

A foreign manufacturer is an establishment in any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States. [§807.40(a)]

A foreign establishment has a set of obligations under §807.40 and §807.41 including:

- Establishment registration
- Device listing
- Identifying one and only one US Agent
- Identify any importer, defined in §807.3(x), of the establishment's devices
- Specify which listed products each importer receives
- Identify any person who imports or offers for import, defined in §807.3(y), of the establishment's devices
- Submit the current premarket submission number for each device being imported or offered for import by the named individuals or organizations

Importer
Initial importer means any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the 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. [§807.3(g)]

Importer means, for purposes of [Part 807], a company or individual in the United States that is an owner, consignee, or recipient, even if not the initial owner, consignee, or recipient, of the foreign establishment's device that is imported into the United States. An importer does not include the consumer or patient who ultimately purchases, receives, or uses the device, unless the foreign establishment ships the device directly to the consumer or patient. [§807.3(x)]

Person who imports or offers for import means, for purposes of [Part 807], an agent, broker, or other entity, other than a carrier, that the foreign establishment uses to facilitate the import of its device into the United States. [§807.3(y)]

Following §807.20(a)(5) an initial importer must register. An initial importer can list by submitting the name and address of the manufacturer. This assumes the initial importer did not either initiate or develop the specifications for the device or repackage or relabel the device.

Initial importers are also subject to Medical Device Reporting (MDR) under 21 CFR Part 803, Reports of Corrections and Removals under 21 CFR Part 806, and Medical Device Tracking under 21 CFR Part 821, if applicable. Under the MDR regulations, importers are required to report incidents in which a device may have caused or contributed to a death or serious injury as well as report certain malfunctions. The importers must maintain an MDR event file for each adverse event. All product complaints (MDR and nonMDR events) must be forwarded to the manufacturer. Under Medical Device Tracking requirements, certain devices must be tracked through the distribution chain. [Source: UCM050126]