Importing Medical Devices and Radiation-Emitting Electronic Products into the U.S.

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Overview
The United States (U.S.) Food and Drug Administration (FDA) is responsible for ensuring that medical devices (including in vitro diagnostics) and radiation-emitting electronic products comply with applicable U.S. regulations when offered for importation into the United States. Foreign establishments must comply with these applicable regulations before, during, and after the medical device or radiation-emitting electronic product is imported into the United States or territory. FDA does not recognize regulatory authorizations from other countries. The product must meet the applicable FDA regulation.

Medical Devices
FDA verifies and enforces applicable medical device requirements at the time a medical device is imported or offered for import into the United States. FDA’s Center for Devices and Radiological Health (CDRH) is responsible for overseeing the medical device program.

Foreign Manufacturers of Medical Devices
A foreign manufacturer is a manufacturer located outside of the United States. Foreign manufacturers must meet applicable U.S. regulations in order to import a device into the U.S.

The basic regulatory requirements include:

- Establishment registration
- Medical Device Listing
- Quality System
• Premarket Notification [510(k)], unless exempt, or Premarket Approval

• Labeling

• Medical Device Reporting.

A foreign manufacturer must designate a United States agent (/medical-devices/device-registration-and-listing/us-agents) as a part of its initial and updated registration information. A foreign manufacturing site is subject to FDA inspection, medical device tracking (when required), and adverse event reporting.


**Initial Importers of Medical Devices**

An initial importer is defined in Title 21 Code of Federal Regulations (21 CFR) Part 807.3(g) as 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.

An initial importer of a medical device is required to comply with the following regulatory requirements:

• Establishment registration

• Medical Device Reporting (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) (MDR) (21 CFR 803)

• Reports of Corrections and Removals (/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices) (21 CFR 806)

• Medical Device Tracking (/medical-devices/postmarket-requirements-devices/medical-device-tracking) (21 CFR 821), where applicable.

Under the MDR regulations, an importer is required to report incidents in which a device may have caused or contributed to a death or serious injury as well as certain malfunctions. An importer must maintain an MDR event file for each adverse event. All product complaints including MDR and non MDR events, must be forwarded to the manufacturer. Under the Medical Device Tracking regulation, certain devices must be tracked through the distribution chain.

**Radiation-Emitting Electronic Products**

**Foreign Manufacturers of Radiation-Emitting Electronic Products**


A foreign manufacturer submits a radiation safety product report to FDA for review. Upon receipt, FDA assigns the report an accession number. An accession number is a unique identifier for the product safety report maintained in an FDA database. An importer may submit a radiation safety product report on behalf of a foreign manufacturer.


**Importers of Radiation-Emitting Electronic Products**

An importer may submit a radiation safety product report on behalf of a manufacturer. An importer of a radiation-emitting electronic product subject to a performance standard is required to send to FDA a written declaration on “Declaration of Products Subject to Radiation Control Standards,” Form FDA 2877. The importer must also provide import entry information, including an accession number, if appropriate, through U.S. Customs and Border Protection (CBP) to FDA.

**Import Process**

All medical devices imported into the United States (U.S.) must meet the regulatory requirements of both the U.S. Bureau of Customs and Border Protection (CBP) and FDA. Products that do not meet FDA regulatory requirements may be detained upon entry.
CBP administers the Tariff Act of 1930 as amended. The primary duties include: assessment and collection of all duties, taxes, and fees on imported merchandise, administering and reviewing import entry forms, enforcing CBP and related laws, and administering certain navigation laws and treaties. FDA and CBP have an agreement for the cooperative enforcement of the Food, Drug, and Cosmetic Act, Section 801, Title 21 U.S.C. 381.

An entry for an FDA regulated product that is filed with CBP, will also be electronically submitted to FDA for review. An importer or customs broker is required to submit required entry information to CBP through the Automated Commercial Environment (ACE) system.

The required entry information includes:

- country of origin
- importation product code, which is a combination of the FDA panel code and FDA product code
- importer product description
- manufacturer
- shipper
- applicable affirmations of compliance codes
- Harmonized Tariff Schedule (HTS) code for the product described in the importing documents.

The HTS code is a classification code used to provide the applicable tariff rates and statistical categories for items imported into the U.S. For questions and guidance on tariff rates, please contact your local CBP Port of Entry (https://www.cbp.gov/contact/ports).

You may expedite the entry review process by submitting accurate and complete information at the time of filing and by responding to requests for additional information in a timely manner.

Import for Export
An entity may import (bring into the United States) device parts, components, subassemblies, etc., for further processing or incorporation into unapproved devices which are to be subsequently exported (brought outside of the United States). An entity may not import a finished device that is not legally marketed in the United States, even if the device is to be imported into the United States solely for subsequent export. A finished medical device that is legally marketed in the United States has a Premarket Notification [510(k)] clearance, a De Novo granted, a Premarket Approval application approval, or is exempt. An entity may not use the “Import for Export” provision for warehousing articles in the United States.

More information about Import for Export (/industry/import-basics/import-export-overview).

Personal Importation

A personal importation is the import of an up-to-90-day supply of a medical device not for further sale or distribution into the United States. These devices may be carried in a baggage or shipped by courier or international mail. Drop shipping is the importation of a U.S. legally marketed device for one person.

References

- Import Procedures, Regulatory Procedures Manual (Chapter 9) (/media/71776/download)
- Imports, Investigations Operations Manual (Chapter 6) (/media/75256/download)
- Import Alerts (/industry/actions-enforcement/import-alerts)
- Import Program (/industry/import-program-food-and-drug-administration-fda)

Compliance Policy Guides

- Export of FDA Regulated Products from U.S. Foreign Trade Zones (/inspections-compliance-enforcement-and-criminal-investigations/compliance-policy-guides/cpg-sec-
110200-export-fda-regulated-products-us-foreign-trade-zones)
Compliance Policy Guide, Section 110.200 (CPG 7150.11)

Compliance Policy Guide, Section 110.500 (CPG 7153.10)

- FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses or on Bonded Carriers (/inspections-compliance-enforcement-and-criminal-investigations/compliance-policy-guides/cpg-sec-110600-fda-authority-over-products-foreign-origin-located-foreign-trade-zones-bonded)
Compliance Policy Guide, Section 110.600 (CPG 7150.14)

Compliance Policy Guide, Section 110.700 (CPG 7153.08)

Compliance Policy Guide, Section 110.800 (CPG 7150.04)

Compliance Policy Guide, Section 110.900 (CPG 7150.15)

Regulations 21 CFR 1, Subpart E--Imports and Exports

- Sec. 1.83 - Definitions

- Sec. 1.90 - Notice of sampling

- Sec. 1.91 - Payment for samples
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1.91)

- Sec. 1.94 - Hearing on refusal of admission
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1.94)

- Sec. 1.95 - Application for authorization to relabel and recondition
  (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1.95)
• Sec. 1.96 - Granting of authorization to relabel and recondition (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1.96)
• Sec. 1.97 - Bonds (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1.97)
• Sec. 1.99 - Costs chargeable in connection with relabeling and reconditioning inadmissible imports (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1.99)