

Importing Medical Devices into the United States

Slide 1

Hello, my name is Terri Garvin. I am a Consumer Safety Officer in the Division of Industry and Consumer Education at FDA's Center for Devices and Radiological Health, or CDRH. Welcome to CDRH Learn, CDRH's resource for multimedia industry education. The title of this presentation is, "Importing Medical Devices into the United States."

Slide 2

Did you know that in 2017, medical devices made up the largest FDA product type imported into the United States? 49% of all FDA regulated imports were medical devices. After viewing this program, I hope that you will have a better understanding of the Import process and the entry information needed to successfully import your devices without delay.

Slide 3

The learning objectives for this module are to describe the import entry process for medical devices and to recognize common entry errors that may lead to import delays.

Slide 4

This slide shows a flowchart that describes the FDA Import Entry Process. Over the course of the next few slides, I will present this process beginning with the submission of the required entry data by your customs broker through the final disposition of your entry.

Slide 5

As noted in the previous slide, the filer obtains the data required by Customs and Border Protection, or CBP, and submits it to his or her custom's broker in accordance with Title 19 Code of Federal Regulations Part 142. Customs Brokers are responsible for using reasonable care to enter, classify, and determine the value of imported goods. They are also responsible for providing any other information necessary to enable CBP to properly assess duties and determine other applicable legal requirements.

The Customs Broker determines the classification of the import using the Harmonized Tariff Schedule, or the HTS Code. The HTS Code is used to determine the tariff duties to be assessed and to flag which imports are subject to FDA Admissibility review. The Customs Broker is responsible for entering this data into CBP's Automated Commercial Environment, or the ACE System.

Slide 6

Once the entry has been filed with CBP, CBP then performs syntax data validation.

Slide 7

CBP conducts syntax validation of import entry or article lines by verifying each entry line for data completeness and determines the entry status using "other government agency" or OGA Flags in accordance with Title 19 CFR Section 142.42. Entry lines regulated by the FDA receive an FDA OGA Flag. If there is incomplete data, the entry is returned to the filer.

Slide 8

Presented on this slide is a table showing the flags associated with FDA regulated commodities. As you can see, the file descriptor, FD2, indicates that the article is under FDA's jurisdiction.

Slide 9

At this point in the entry process, once CBP has performed the syntax data validation, FDA then screens the data specific to the device for entry into the U.S.

Slide 10

During the screening process, FDA reviews the entry and determines if the required data are present. If there are missing data, FDA may request additional information needed to meet regulatory requirements, or request a sample for examination. Data or documents submitted in response to a request for additional information may be uploaded electronically using FDA's Import Trade Auxiliary Communications System, or ITACS. You can use ITACS to determine the status of your entry.

Slide 11

Upon completion of the import entry screening, FDA generates an import disposition and sends it to CBP.

Slide 12

To generate the import disposition of a medical device entry, FDA must first review the data required for all FDA regulated products, as well as the specific data required for medical devices.

Slide 13

FDA reviews the entry for required data. This includes product-identifying information, which consists of the FDA Country of Production, the Complete FDA Product Code, and the Complete Intended Use Code. The product code is generated using the product code builder. The complete intended use code is found in Appendix R of FDA's Supplemental Guide. FDA also reviews the Contact Information for the Importer of Record, which includes their email address and telephone number.

Slide 14

In accordance with 21 CFR Section 1.76, all device entries require the following information, if applicable: registration and listing number; investigational device information; premarket number; or component affirmation.

Slide 15

Additionally, the entry must also include affirmations of compliance for specific device types as applicable. This device types are: Lead wire/patient cables, Impact resistance lenses, and Convenience Kits. And specific to radiation-emitting electronic products, 21 CFR Section 1.77 requires that an ACE filer submit all of the declarations in Form 2877, indicating that applicable performance reports have been submitted.

Slide 16

To determine which of the data elements addressed in 21 CFR Section 1.76 are applicable to your entry, you must first determine the classification of the device. This can be done by using the classification database to find your device and the associated regulatory requirements. The Affirmation of Compliance Codes are used to then demonstrate the regulations applicable to your device. A link to the database is included on this slide.

Slide 17

This is a screen shot of CDRH's Product Classification Database. The device search field is highlighted on the screen. Enter either a general name for the device or a term that describes its intended use. The next slide provides an example of one of the product records which resulted from a search using the term "orthosis".

Slide 18

Note the red highlighted sections of this device record. Device records provide the device name and description, the 3-letter product code assigned to the device, the device submission type, and Information regarding registration and listing requirements as indicated in the red highlighted box at the bottom of the screen.

Slide 19

Use the device information found in the product classification database record to identify the premarket number, if any. Identify the premarket submission type which can be a Premarket notification, a Premarket application, a Humanitarian Device Exemption, or a De Novo Classification. The product may be exempt from premarket submission requirements and instead of a premarket number, you will identify your product by the 3-letter product code.

Slide 20

Use the device classification information to identify both the Foreign Manufacturer's establishment registration and device listing numbers, the Foreign Exporter's establishment registration and device listing numbers, or the Initial Importer's establishment registration number. Initial importers are not required to list.

Slide 21

Affirmations of Compliance provide CDRH with the information it uses to make admissibility determinations. There are specific codes for medical devices and radiological health products. The next two slides present the codes for the respective product types.

Slide 22

The codes for medical devices are provided on this slide. The highlighted codes represent the ones most often required for entry. The Code DEV represents the registration number for the foreign manufacturer, the code LST represents the device listing number and the code PM number represents the premarket submission number associated with a particular device.

Slide 23

This slide lists the codes associated with Radiological Health products. In the table, Code IFE represents, "Import for Export". This code can be used for medical devices as well. It indicates that the device will be imported for further processing, and upon completion of that processing, it will be exported.

Slide 24

Thus far, we identified the data requirements for imports in general, as well as the requirements specific to CDRH's regulatory requirements. This is an example of an entry that is identified as a standard import of a foreign manufactured device. The intended use code for such an entry is 081.001. Further identification of this device is needed to determine which codes are considered mandatory, conditional or optional.

Slide 25

We discussed the entry process which begins with FDA screening the required data for the entry. Once FDA has completed its screening for the required data, it continues with the Import Disposition by determining the notice of action. The notice of action will be either to release the product, request additional information, request a sample for evaluation, or request detention of the entry. After FDA has determined the notice of action, FDA will then issue the notice to CBP and the Importer of Record.

Slide 26

Going back to our flow chart, once FDA generates the import disposition and sends it to CBP, CBP then sends the message to the broker and others as required.

Slide 27

In addition to the Customs Broker, CBP also sends an electronic disposition message to the Filer or Importer of Record and to the Owner. This completes the FDA import entry process.

Slide 28

As you can see, the import entry process involves a number of steps, and not surprisingly, we see a number of common errors that occur. Let's review these now so that you can avoid these errors.

Slide 29

Some common entry errors include submitting the incorrect Affirmation of Compliance code, the incorrect manufacturer information, the incorrect product code, the incorrect product quantity, or incomplete information. If you can avoid these errors, you're much more likely to be successful in importing your medical devices products without running into problems along the way. More information about common entry errors may be found at the link on this slide.

Slide 30

Let's review what we've covered in this module. FDA reviews import entry data for complete and correct information associated with the product submitted for entry. Regulatory requirements are based partly on product classification.

Affirmation of Compliance codes correspond with these regulatory requirements. And finally, entry errors, due to incomplete data or other reasons, may lead to import delays.

Slide 31

CDRH provides multiple opportunities for industry education. CDRH Learn is an innovative educational tool, which consists of learning modules describing many aspects of medical device and radiation emitting product regulations, covering both premarket and post-market topics. Modules are provided in various formats, including videos, audio recordings, and slide presentations.

Device Advice is a text-based resource that explains many aspects of medical device laws, regulations, guidance, and policies, covering both premarket and post-market topics.

In addition, the Division of Industry and Consumer Education (D-I-C-E) answer's questions, by phone and email, from industry and consumers related to medical devices. The web links and contact information to these resources are provided on this slide.

Slide 32

After viewing this presentation, your call to action is to ensure that prior to submitting your entry for import, you ensure that your product meets U.S. Regulatory Requirements, that the proper parties are registered and have completed a device listing, if required; and that applicable Entry data are provided to your Customs Broker. Thank you for watching.
