# Importing Medical Devices Into the United States

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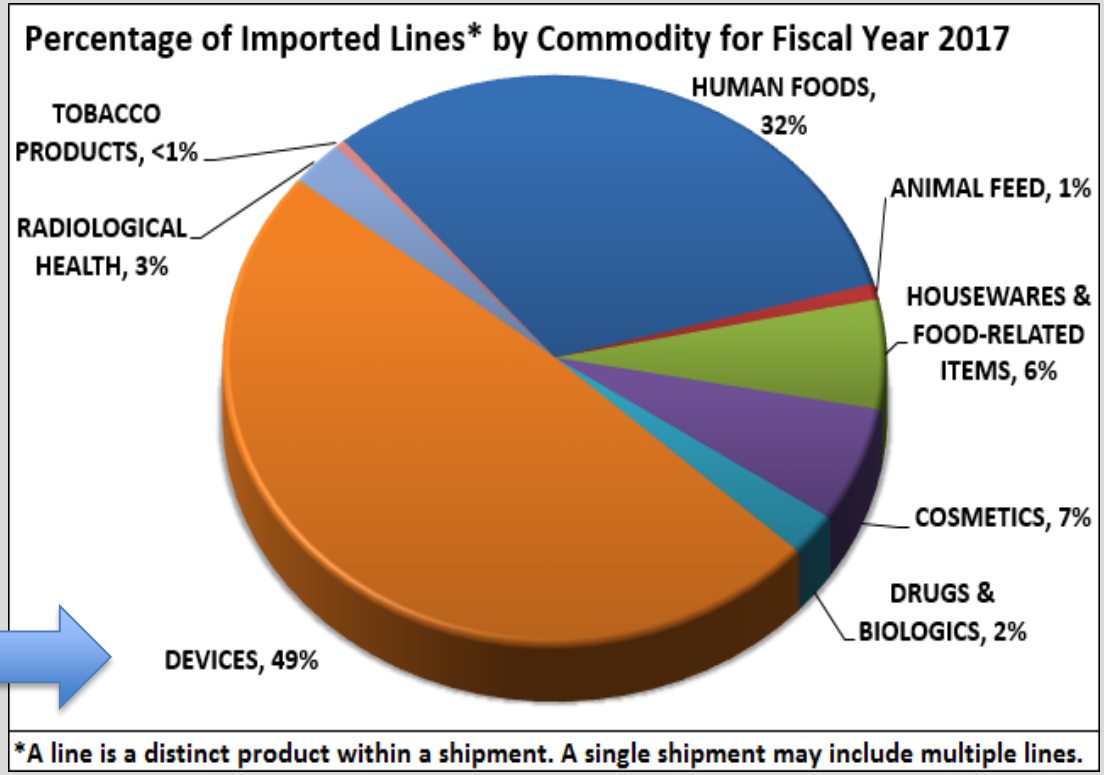
# Annual Percentage of Imported FDA Commodities

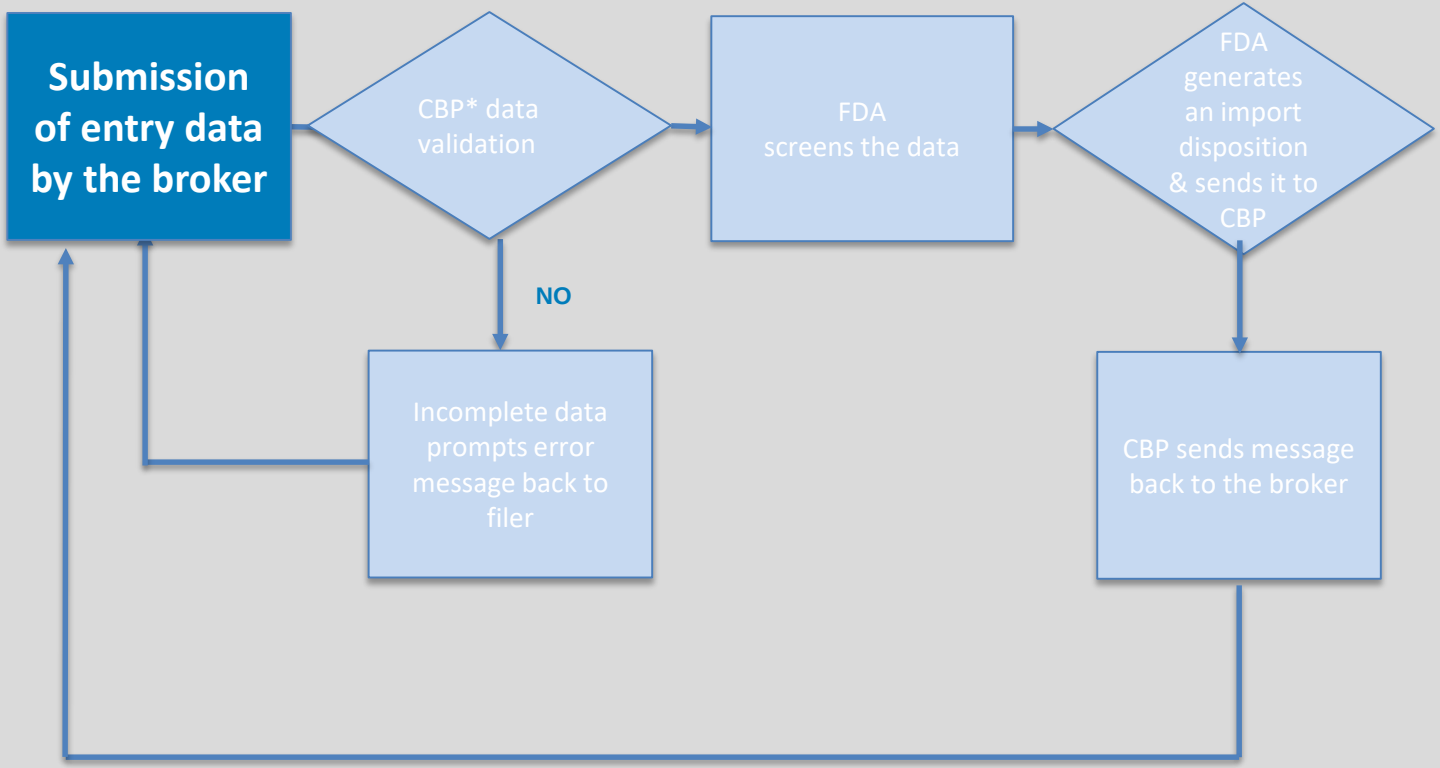


# Learning Objectives

1. Describe the import entry process

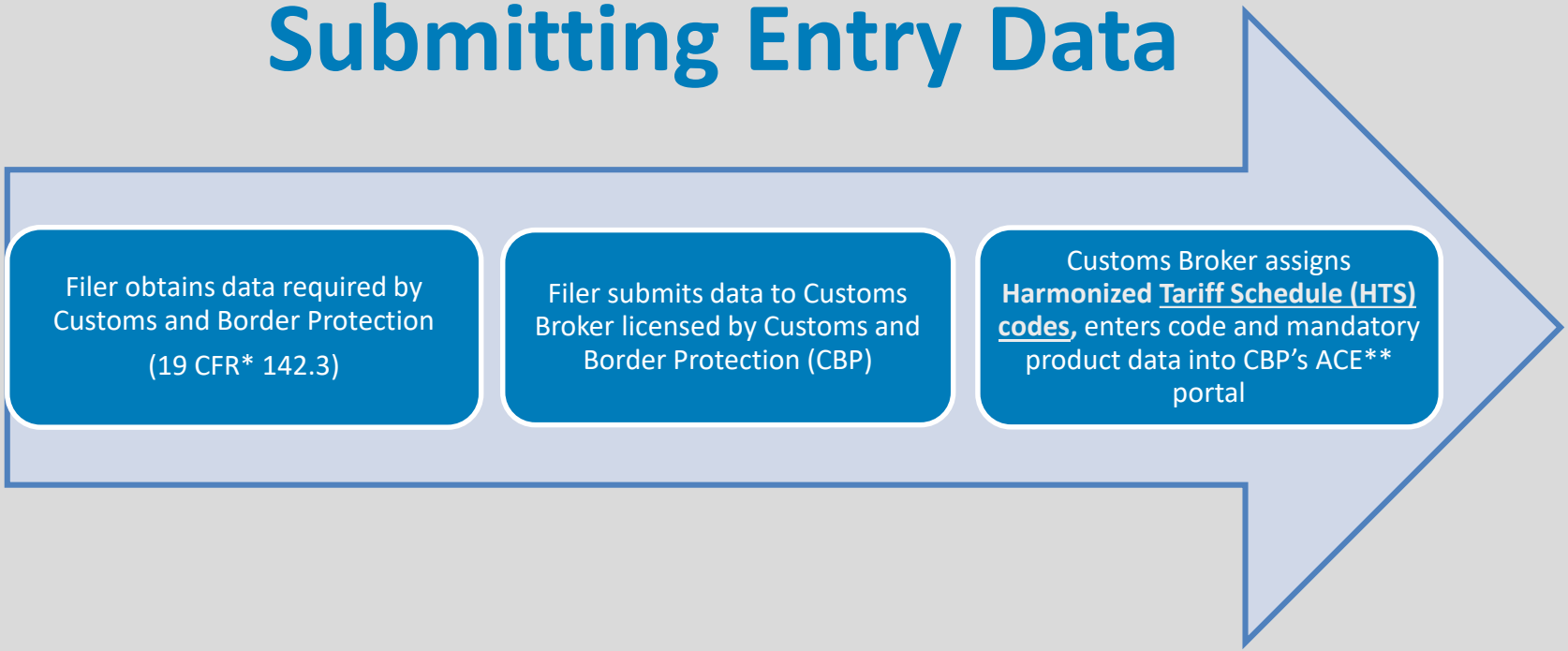
2. Identify common entry errors that may lead to import delays

# FDA Import Entry Process



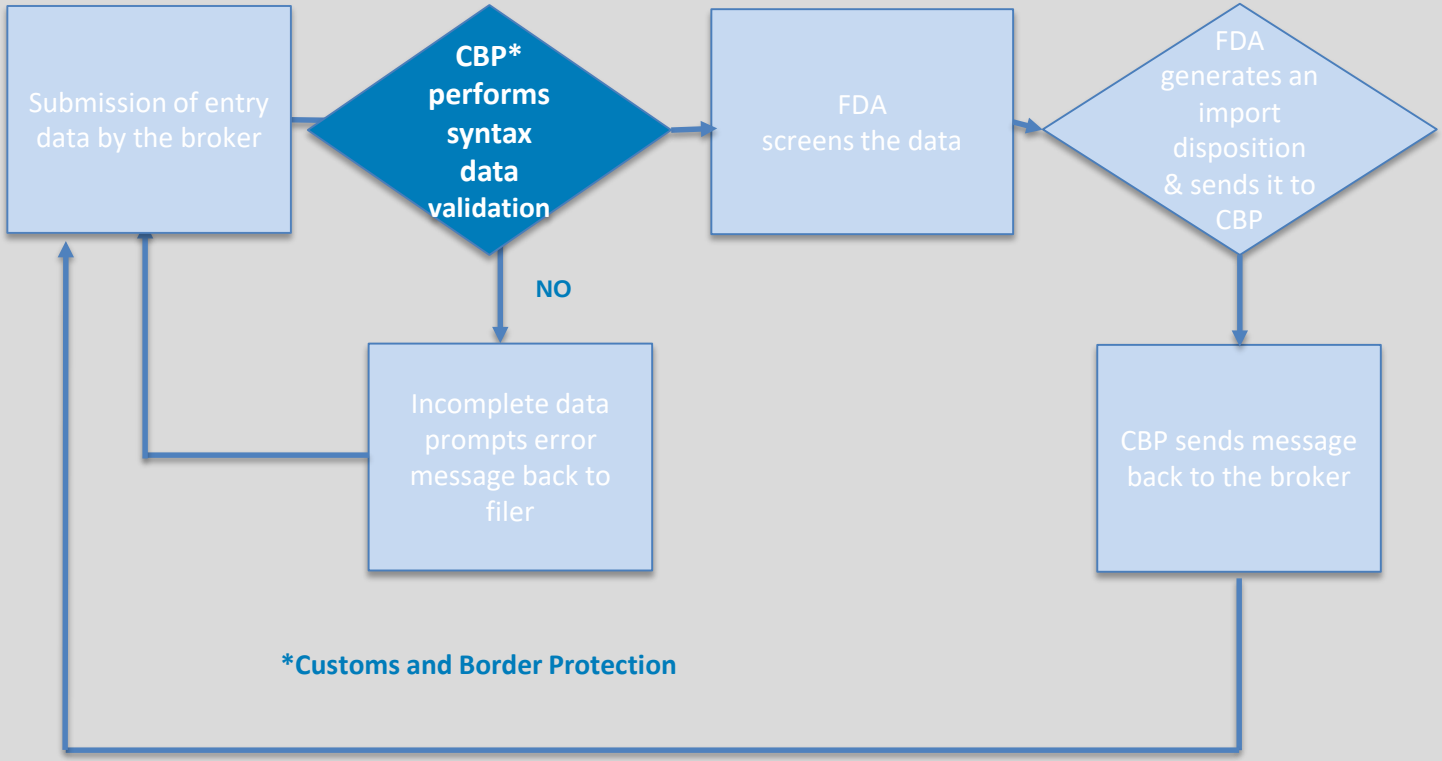
# FDA Import Entry Process:

## Submitting Entry Data




*Code of Federal Regulations
**Automated Commercial Environment

# FDA Import Entry Process



# CBP Data Validation

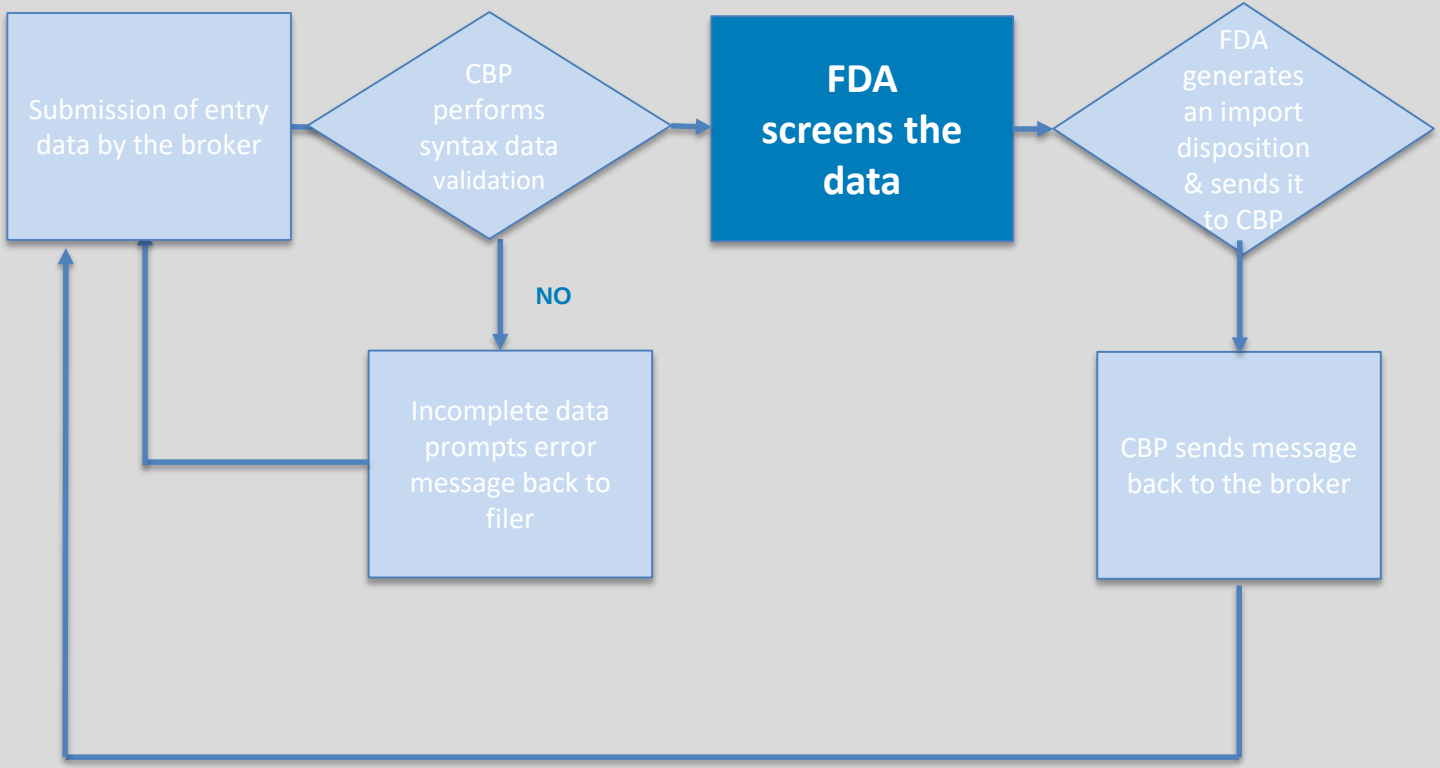
- CBP conducts syntax validation of import entry (article) lines:
  - Verify each entry (article) line for data completeness
  - Determine entry (article) status using “other government agency” (OGA) Flags
    - Entry (article) lines regulated by FDA receive FDA OGA Flag
  - If data are incomplete, entry (article) is returned to filer

# CBP Data Validation: FDA Flags

| FDA FLAG | Is it regulated? | Example |
|---|---|---|
| FD*1 | May or may not be regulated by FDA: If regulated by FDA, submit entry information; if not regulated by FDA, disclaim | Certain chemicals used in manufacturing drug products vs. industrial use; safety goggles for medical use vs. non-medical use |
| **FD2** | **Regulated by FDA, but is not food: Submit entry information** | **Medical Devices, Drugs, Tobacco, and Cosmetics** |
| FD3 | May or may not be a food product: If yes, submit Prior Notice (PN) and entry information; if no, disclaim | Salt used for flavoring food vs salt used for treating road surfaces |
| FD4 | Food product: Submit PN and entry information | Fish and seafood, live food animals, dairy products, shell eggs, fruits, vegetables, food and feed ingredients, food and feed additives, infant formula, beverages (including alcoholic beverages and bottled water), bakery goods, snack foods, candy, canned foods, and dietary supplements and dietary ingredients. |

***An FDA flag is assigned a file descriptor (FD) number, i.e. FD1**

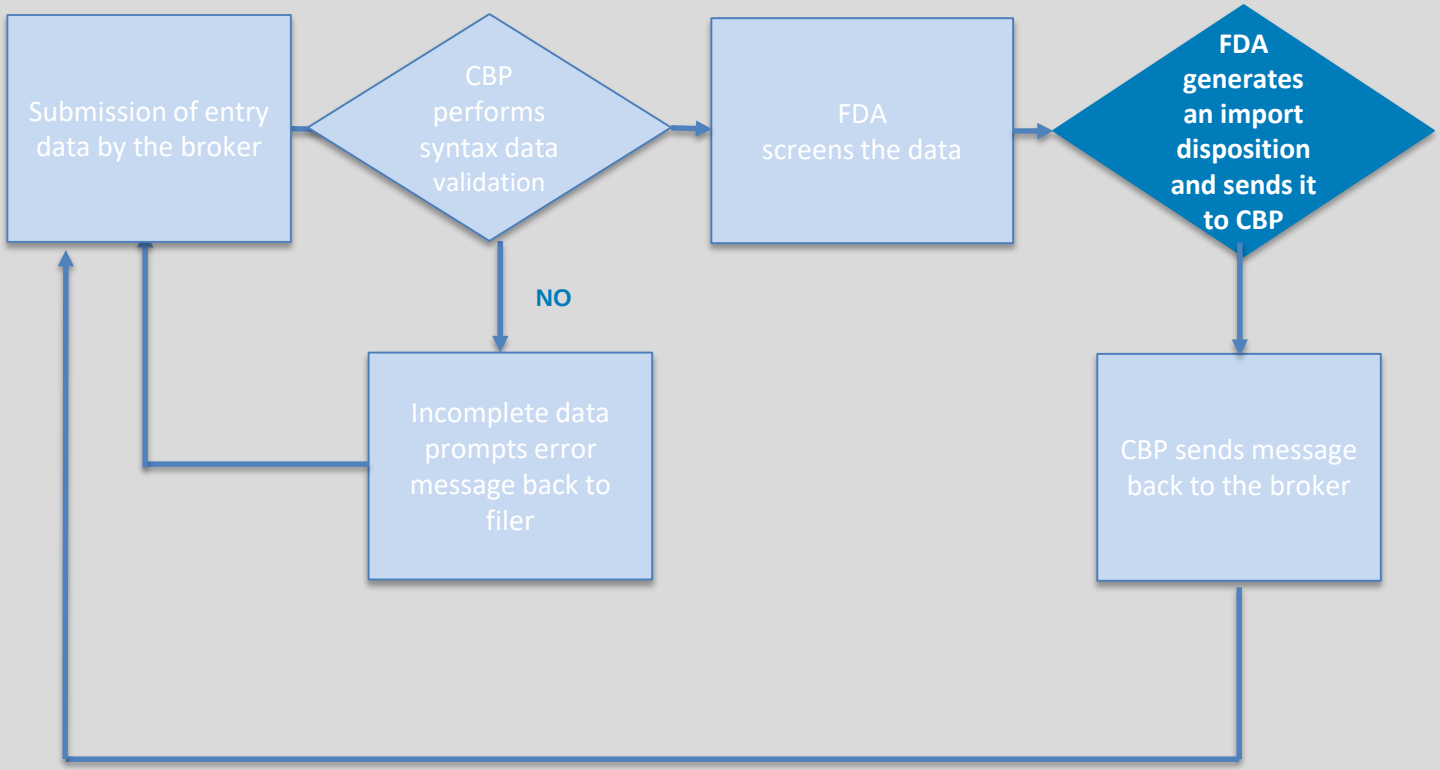
# FDA Import Entry Process



# FDA Screens the Data

- FDA Reviews the Entry (Article) Data
- FDA determines if all required data to meet regulatory requirements have been provided
  - FDA may request additional data needed to meet regulatory requirements or request sample for examination
  - Data can be uploaded electronically using FDA's Import Trade Auxiliary Communications System (ITACS)
  - ITACS can also be used to check the status of an entry (article)

# FDA Import Entry Process



# Import Disposition

## To generate an import disposition:

1. FDA reviews entry (article) for
   - ✓ Data required for all FDA regulated articles (products), (21 CFR 1.72)
   - ✓ Data Required by CDRH*for medical devices, (21 CFR 1.76)

*Center for Devices and Radiological Health

# Import Disposition

## Data required for all FDA regulated articles (product)

21 CFR 1.72

- **Product-identifying information:**
  - FDA country of production
  - Complete FDA product code
  - Full intended use code
- **Importer of Record Contact Information**
  - Email address and telephone number

# Import Disposition

## If applicable, Data required by CDRH for Medical Devices 21 CFR 1.76

- Registration and Listing Number
- Investigational Device Information
- Premarket number
- Component affirmation

# Import Disposition

**If applicable, data required for Medical Devices**

21 CFR 1.76

- Lead wire/patient cable performance standard affirmation
- Impact resistance lens affirmation of compliance with 21 CFR 801.40
- Convenience kit affirmation

**If applicable, data required for Radiation-Emitting Electronic Products**

21 CFR 1.76

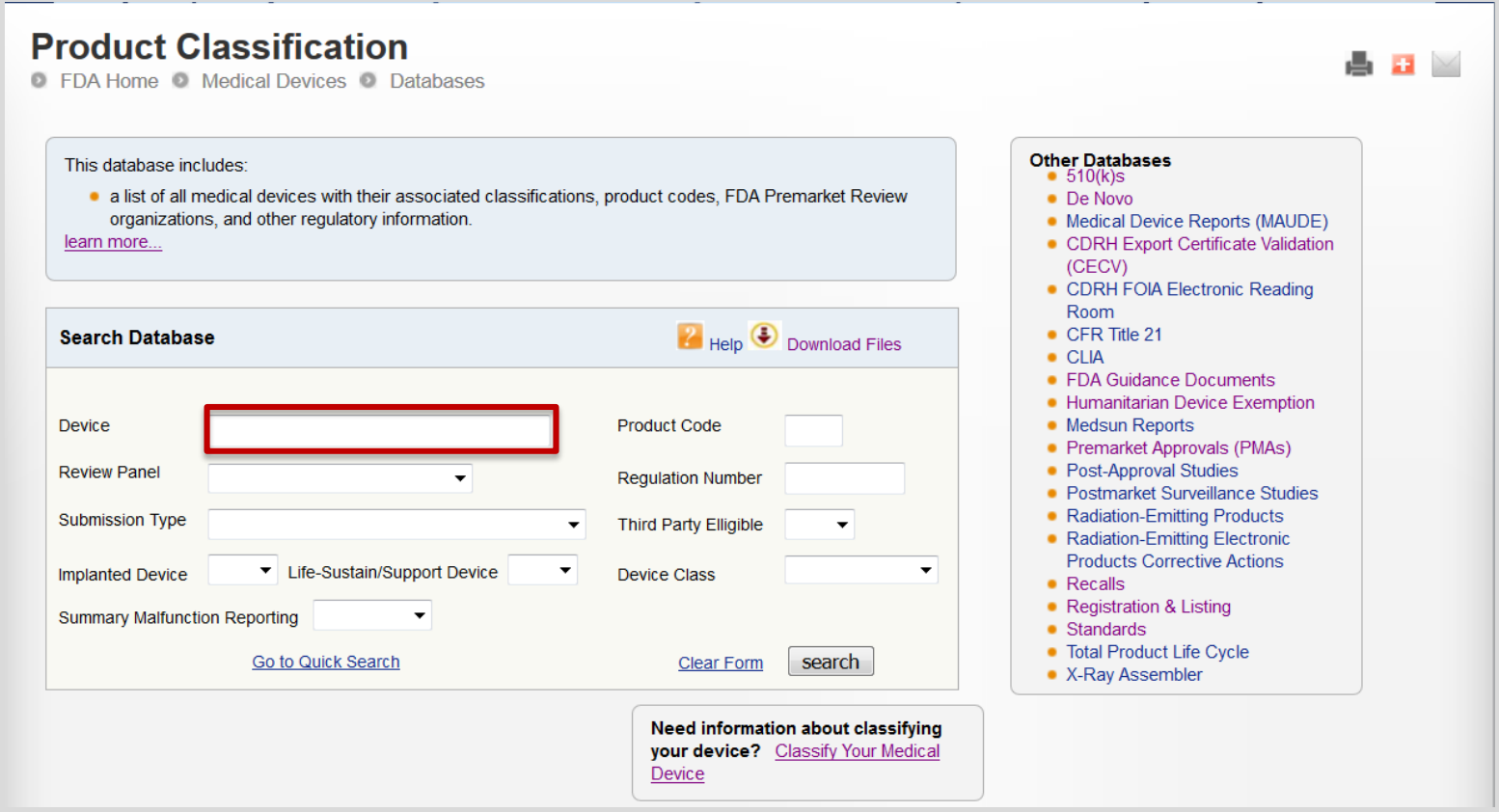
- Radiation-emitting electronic products declarations in Form 2877

# Import Disposition

## Data required by CDRH for Medical Devices

- Determine regulatory requirements based on product classification
- Use CDRH's Product Classification Database to identify product classification and other regulatory requirements
- Use Affirmation of Compliance Codes (A of C) to designate regulatory requirements

# CDRH Device Regulatory Requirements: Product Classification Database



New Search | Back to Search Results

| | |
|---|---|
| **Device** | Orthosis, Corrective Shoe |
| **Regulation Description** | Limb orthosis. |
| **Regulation Medical Specialty** | Physical Medicine |
| **Review Panel** | Physical Medicine |
| **Product Code** | KNP |
| **Premarket Review** | Neurological and Physical Medicine Devices (OHT5)<br>Neuromodulation and Physical Medicine Devices (DHT5B) |
| **Submission Type** | 510(K) Exempt |
| **Regulation Number** | 890.3475 |
| **Device Class** | 1 |
| **Total Product Life Cycle (TPLC)** | TPLC Product Code Report |
| **GMP Exempt?** | Yes |

**Note:** This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), *as long as the device is not labeled or otherwise represented as sterile.*

| | |
|---|---|
| **Summary Malfunction Reporting** | Eligible |

**Note:** FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

| | |
|---|---|
| **Implanted Device?** | No |
| **Life-Sustain/Support Device?** | No |
| **Third Party Review** | Not Third Party Eligible |

# Example: Product Classification Record

# CDRH Regulatory Requirements: Product Classification Database

**Use Device Classification Information To:**

- Identify Premarket Number:
  - ✓Premarket Notification [510(k)]
  - ✓Premarket Approval (PMA) Application
  - ✓Humanitarian Device Exemption (HDE)
  - ✓De Novo Classification
  - ✓Exempt (3-letter product code)

# CDRH Regulatory Requirements: Product Classification Database

## Use Device Classification Information To:

- Identify Registration and Listing Numbers for:
  - ✓Foreign manufacturer
  - ✓Foreign exporter
  - ✓Initial importer (registration only)

# CDRH Regulatory Requirements: Affirmation of Compliance Codes

**Use Affirmation of Compliance (A of C) codes to designate regulatory requirements**

- A of C Codes for Medical Devices
- A of C Codes for Radiological Health Products

# Example: Medical Device Affirmations of Compliance Codes

| Devices | | |
|---|---|---|
| **Code** | **Affirmation of Compliance** | **Qualifier?** |
| **CPT** | Component Identifier | N |
| **DA** | New Drug Application Number or Abbreviated New Drug Application Number or Therapeutic Biologic Application Number | Y |
| **DDM** | Device Domestic Manufacturer | Y |
| **DEV** | Device Foreign Manufacturer Registration Number | Y |
| **DFE** | Device Foreign Exporter Registration Number | Y |
| **DI** | Device Identifier | Y |
| **ERR** | Entry Review Requested | N |
| **IDE** | Investigational Device Exemption Number | Y |
| **IFE** | Import For Export | N |
| **IND** | Investigation New Drug Application Number | Y |
| **IRC** | Device Impact Resistance Lens Certification | N |
| **KIT** | Device Imported Kit of Finished Devices | N |
| **LST** | Device Listing Number | Y |
| **LWC** | Electrode Lead Wire or Patient Cable | N |
| **PM#** | Device Premarket Number | Y |

# Example: Radiological Health Products Affirmations of Compliance Codes

| Radiological Health Products | | |
|---|---|---|
| Code | Affirmation of Compliance | Qualifier? |
| ACC | Accession Number | Y |
| ANC | Annual Report Accession Number | Y |
| CCM | Name of the Certified Component Manufacturer | Y |
| ERR | Entry Review Requested | N |
| IFE | Import For Export | N |
| MDL | Model Number | Y |
| RA1, RA2, RA5, RA7 | Rad Health Product Affirmation A (FD2877) | Y |
| RA3, RA4, RA6 | Rad Health Product Affirmation A (FD2877) | N |
| RB1 | Rad Health Product Affirmation B (FD 2877) - transmit with ANC or ACC | N |
| RB2 | Rad Health Product Affirmation B (FD 2877) | Y |
| RC1 | Rad Health Product Affirmation C (FD 2877) | N |
| RC2 | Rad Health Product Affirmation C (FD 2877) | Y |
| RD1, RD2 | Rad Health Product Affirmation D (FD 2877) | N |
| RD3 | Rad Health Product Affirmation D (FD 2877) | Y |

# Example: Import Scenarios

| Intended Use (see PG01 for definitions) | Import Scenarios | Mandatory Affirmations | Conditional* Affirmations | Optional Affirmations |
|---|---|---|---|---|
| 081.001 or UNK | -Standard import of a foreign-manufactured device, accessories, or components regulated as a finished device<br>-Import of refurbished device<br>-Import of a reprocessed device | DEV, DFE, LST | IRC, LWC, PM# | DI |
| 081.002** | Import of a foreign-manufactured device for domestic refurbishing | DEV, DFE, LST | IRC, LWC, PM# | DI |

*Conditional affirmations are required if applicable to the product being declared for entry

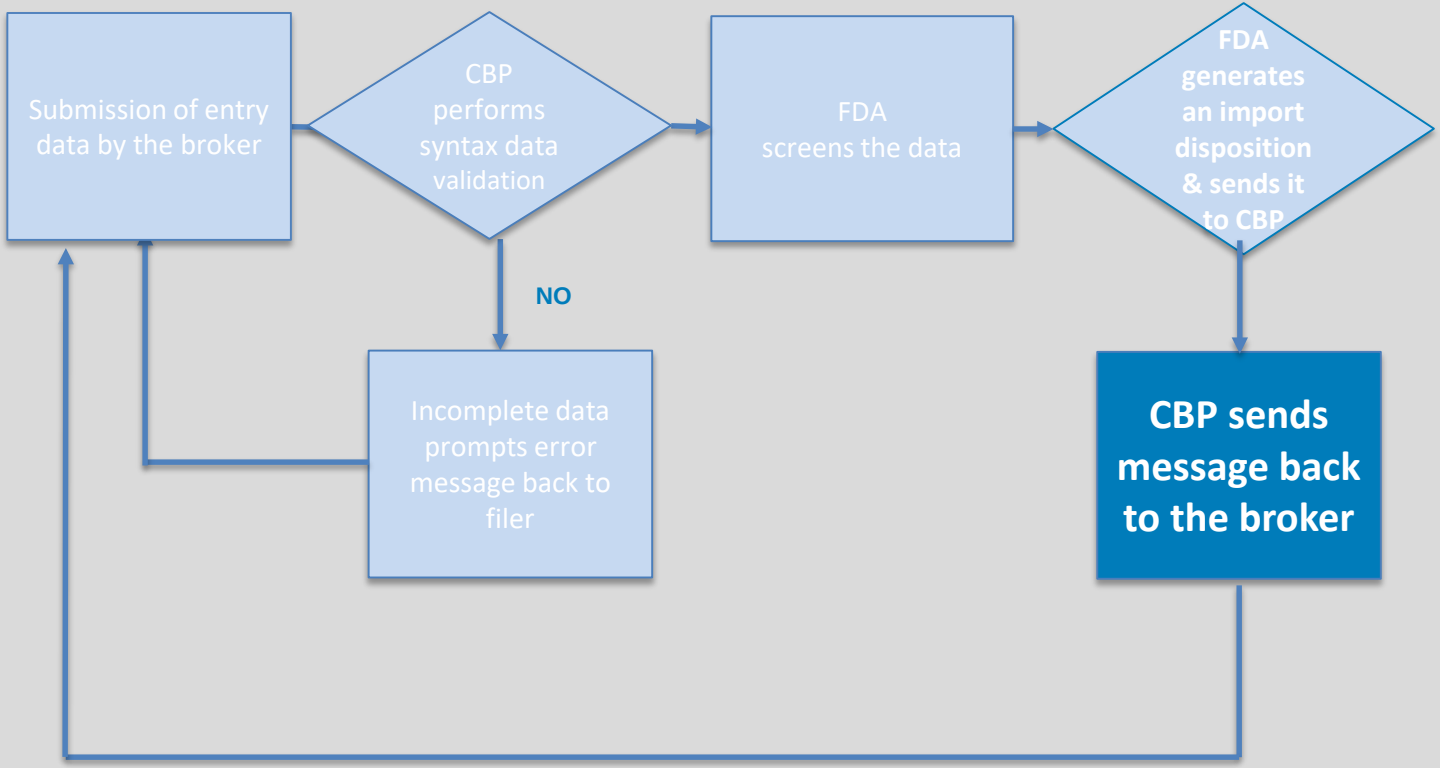
**Additional info may be needed at time of entry for FDA to make a final admissibility decision

# Import Disposition

**To generate an import disposition:**

1. FDA reviews entry (article) for
   - ✓ Data required for all FDA regulated articles (products), (21 CFR 1.72)
   - ✓ Data Required by CDRH*for medical devices, (21 CFR 1.76)
2. FDA determines Notice of Action:
   - ✓ Release the product
   - ✓ Request additional information or sample evaluation; or
   - ✓ Request detention of product
3. FDA issues Notice of Action to CBP and Importer of Record

# FDA Import Entry Process



# CBP Sends Message

**CBP sends electronic disposition message to:**

- Customs Broker
- Filer/Importer of Record
- Owner or Consignee

# Common Entry Errors

# Common Entry Errors

**Submitting**

- Incorrect Affirmation of Compliance Codes
- Incorrect Manufacturer Information
- Incorrect Product Code
- Incorrect Product Quantity
- Incomplete Information

www.fda.gov/industry/regulated-products/medical-device-common-entry-errors

# Summary

- FDA reviews medical device import information
- Regulatory requirements are based partly on product classification
- Affirmation of Compliance codes correspond with regulatory requirements
- Entry errors may lead to import delays

# Providing Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 100 modules - videos, audio recordings, PowerPoint presentations, software-based “how to” modules
   - accessible on your portable devices: **www.fda.gov/CDRHLearn**

2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics: **www.fda.gov/DeviceAdvice**

3. **Division of Industry and Consumer Education (DICE)**
   - Email: DICE@fda.hhs.gov
   - Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4: 30 pm ET)

# Your Call to Action

Prior to importing your products, do these three tasks:

1. Ensure your product meets U.S. regulatory requirements
2. Register and list, if required
3. Provide the applicable entry information to your custom broker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ADMINISTRATION