# FDA – Medical Devices – PGA Filer Data Requirements based on FDA Supplemental Guide

- Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices.
- Medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits
- Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines and medical lasers.
- If a product is labeled, promoted or used in a manner that meets the following definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the Food and Drug Administration (FDA) as a medical device and is subject to premarketing and postmarketing regulatory controls.

**Medical Device Definition**

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

# FDA – Medical Devices – PGA Filer Data Requirements based on FDA Supplemental Guide

**When transmitting an FDA Medical Device, the PGA records that are utilized are:**

| Description |
|---|
| Commercial Description |
| Government Agency Code |
| Government Program Code |
| Government Agency Processing Code |
| Intended Use Code/Intended Use Description |
| Product Code |
| Country of Production/Manufacturing |
| Trade/Brand Name |
| Invoice / Item Description |
| Manufacturer Name, Address, FEI |
| Importer of Record Name, Address, FEI |
| Shipper Name, Address, FEI |
| Delivered to Party Name, Address, FEI |
| Point of Contact Name, Email Address |
| Affirmations of Compliance |
| General Remarks |
| Line Value |
| All Levels of Packaging (PCS must be base unit) |
| Anticipated Arrival Date and Location |
| Disclaimer |

**Commercial Description:** The commercial description of the product. For example, PEDIATRIC TOURNIQUET CUFF SET.

**Government Agency Code**: FDA

**Government Agency Program code for FDA Medical Device PGA Message Sets:**

| *Government Agency Program Code* | *Description* |
|---|---|
| DEV | Medical Devices |

**Government Agency Processing Code:**

| *Government Agency Processing Code* | *Description* |
|---|---|
| RED | Radiation Emitting Devices |
| NED | Non-Radiation Emitting Devices |

### Intended Use Code

For Medical Devices, only one of the following Intended Use Codes may be entered:

### Intended Use Description

This field is used to describe the Intended Use such as 'Sample devices', 'Return shipment', etc

| Intended Use Code | Intended Use Definition | Relevant Medical Device Import Scenarios |
|---|---|---|
| **081.001** | For Human Medical Use as a Medical Device | • Standard import of a medical device, accessories, or components regulated as a finished device<br>• Import of refurbished device<br>• Import of a reprocessed device |
| **081.002** | For Human Medical Use as a Medical Device for Domestic Refurbishing | |
| **081.003** | For Human Medical Use as Medical Device–domestically manufactured device that is part of a medical device convenience kit | |
| **081.004** | For Human Medical Use as a Medical Device –foreign manufactured device that is part of a medical device convenience kit | |
| **081.005** | Importation of a device constituent part (finished device) for use in a medical product regulated under a drug (CDER) application type (e.g., for use in an NDA/ANDA/BLA drug-device combination product). | |
| **100.010** | For Personal Use as a Non-Food Product – for personal use as a medical device | |
| **110.000** | For Public Exhibition or Display as a Non-Food Product | • Includes import of device for trade show |
| **140.000** | For Charitable Organization Use as a Non-Food Product | |
| **151.100** | Component for further manufacturing into a finished medical device | |
| **151.200** | Importation of a device component for use in a medical product regulated under a drug (CDER) application type (e.g., for use in an NDA/ANDA/BLA drug-device combination product). | |
| **170.000** | For Repair of a Non-Food Product | • Repair of medical device and re-exportation |
| **180.010** | For Research and Development as a Non-Food Product - For research and development as a medical device | • Import of research or investigational use in vitro diagnostic device |
| **180.100** | For Research and Development as a Non-Food Product – for bench testing or nonclinical research use | • Import of a device for non-clinical use/bench testing<br>• Import of device sample for customer evaluation |
| **180.200** | For Research and Development as a Non-Food Product – import of a medical device for clinical investigational use | |
| **920.000** | Import of a device that is US goods returned for refund/overstock (to manufacturer) | |

| Intended Use Code | Intended Use Definition | Relevant Medical Device Import Scenarios |
|---|---|---|
| | | |
| **930.000** | Import of a device that is US goods returned for sale to a third party | |
| **940.000** | Import of a Compassionate Use/Emergency Use Device | |
| **950.001** | Import of a single-use device for domestic reprocessing | |
| **950.002** | Import of a multi-use device for domestic reprocessing | |
| **970.000** | Import for Export | • Import of a medical device for further processing and re-exportation<br>• Import of medical device components for further manufacturing into an export only medical device |

**Product Code**

Only one Product Code Number per product is allowed

**FDA Product Code Builder Tutorial:**

http://www.accessdata.fda.gov/scripts/ora/pcb/tutorial/tutorial.cfm

Product Code Must be equal to 7 characters

FDA Product Code Structure:

| Position | 1-2 | 3 | 4 | 5 | 6-7 |
|---|---|---|---|---|---|
| Name | Industry Code (N) | Class Code (A) | Sub Class Code (A or '-') | Process Identification Code - PIC (A or '-') | Product (AN) |

**Country of Production/Manufacturing**

Country of production or source is required for Medical Devices. (ISO Country Code) (define?)

**Trade/Brand Name**

Trade/Brand Name of the Medical Device. For example, Zimmer Reusable Tourniquet Cuff

**Invoice/Item Description**

The medical device detail description. NOT product code description.

**List of Entity Role codes applicable to FDA Medical Device Message Sets:**

| *Data Element* | *Code* | *Description* |
|---|---|---|
| Entity Role Codes | MF | Manufacturer of goods |
| | DEQ | Shipper |
| | FD1 | FDA Importer 1 (Importer of Record) |
| | DII | Device Initial Importer |
| | DP | Delivered To Party |

**Define Roles?**

**Entity Information:**

**Entity Name and Entity Address** (Entity State/Province - Populated ONLY if US or Canada based entities)

**Registration Number**

Additionally, FDA/CDRH prefers to use FEI numbers for identifying the Entity for Medical Devices;

For devices the vast majority of registration numbers (DEV) are FEIs

IF FEI is not available THEN DUNS?

(FEI) THEN Entity Number MUST BE Length from 4 to 10
(DUNS) THEN Entity Number MUST BE Length = 9

**Point of Contact**

| *Data Element* | *Code* | *Description* |
|---|---|---|
| Entity Role Codes | PK | Point of Contact |

Included in this record are the Individual Name, Telephone Number, Fax Number, and Email address. A typical example will be a POC is needed for the Filer. (Define)

| |
|---|
| Individual Name |
| Telephone Number of the Individual |
| Email Address or Fax Number for the Individual |

**Affirmations of Compliance**

The list of Affirmation of Compliance (AoC) codes for FDA-Medical Devices Message Sets is below followed by the scenarios when the AofC' s should be provided:

The FDA Affirmation of Compliance Codes and their descriptions are listed in the Appendix PGA (Food & Drug Affirmation of Compliance, FDA Affirmation of Compliance Codes) of ACE ABI CATAIR publication.

**N=Numeric digits; X=Alphanumeric (need some help with this)**

| ***Code*** | ***Description*** | ***Qualifier*** |
|---|---|---|
| PM# | Device Premarket Number<br>• Premarket Approval (PMA) number (i.e. Pxxxxxx)<br>• Device Premarket Notification Number (PMN) ((510(k)) (i.e. Kxxxxxx)<br>PMN or PMA number database found at:<br>http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm<br>http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm<br>• Product Development Protocols (PDP) number<br>• Humanitarian Device Exemption (HDE) number | Any of the following:<br>P+6N;<br>N+4N, 5N, or 6N;<br>D+6N;<br>H+6N;<br>K+6N;<br>DEN+6N |
| DDM | Device Domestic Manufacturer | 1 - 10N |
| DEV | Device Foreign Manufacturer Registration Number<br>The qualifier for this code should be the device registration number issued by CDRH (Center for Devices and Radiological Health) for the firm manufacturing the product. Note: The DEV should always be associated with the foreign manufacturer. | 1 - 10N |

| | | |
|---|---|---|
| DFE | Device Foreign Exporter Registration Number | 1 - 10N |
| DI | Device Identifier | 6-23X |
| DII | Device Initial Importer | |
| CPT | Component Identifier | Indicator only |
| IFE | Import For Export | Indicator only |
| IDE | Investigational Device Exemption Number | G+6N OR "NSR" |
| IRC | Device Impact Resistance Lens Certification ( Drop Ball Test)<br>▪ This code is used to certify that the filer has on hand the test results or a certificate that shows that the product on the FDA line has met the standards for impact resistance Lens.( sun glasses etc.)<br>▪ Note: Each shipment must have its own test results. | Indicator only |
| KIT | Device Imported Kit of Finished Device | Indicator only |
| LST | Device Listing Number<br>The qualifier for this code should be the device listing number issued by CDRH for the product identified in the FDA Line | A+6N; B+6N; C+6N; D+6N; E+6N; L+6N; Q+6N; R+6N |
| LWC | Electrode Lead Wire Or Patient Cable<br>• This Code should be used when importing electrode lead wires, patient cables, or devices that use them.<br>• The Affirmation indicates that the device does not contain any pre-wired electrodes, electrode lead wires, or patient (transducer) cables | Indicator Only |

**General Remarks**

If submitting general comments then use the Remarks Type Code = GEN (General Remarks). This is a Free form text relevant to the shipment or the commodity. (68 alphanumeric characters allowed)

**Line Value**

The value associated with the PGA line number in whole dollars

**All Levels of Packaging (PCS must be base unit)**

For Medical Device, this is a mandatory PGA input record that provides FDA with data pertaining to Packaging Qualifier, Quantity and Unit of Measure. This record can be repeated up to six (6) times, once for each unique packaging level. The first record is used to describe the largest (outermost) container and the number of containers at this packaging level. The second record is used to describe the contents of the next smallest container. If needed, qualifiers 3-6 are used in a similar manner (largest to smallest container). The final record (base Unit) must describe the actual amount of the product in the smallest container. **(PCS must be base unit)?**

**Anticipated Arrival Date and Location**

This is a mandatory PGA input record that provides data pertaining to the date, time and location of the anticipated arrival information for all FDA products.

**HTS Codes**

| Tariff Flag Code | Tariff Flag Code Definition |
|---|---|
| FD1 | FDA data may be required 801(a) |
| FD2 | FDA data Required 801(a) |
| FD3 | FDA Prior Notice Data may be required 801(m) |
| FD4 | FDA Prior Notice Data is required 801(m) |

Flags do not indicate the FDA program

**Disclaimer:** Code declaring filing does not require a PGA Message Set.

**Valid codes are:**

A = product is not regulated by this agency

B = data is not required per agency guidance

**Codes A and B are NOT allowed if the HTS is flagged as 'Must Be' provided**.

**Document Imaging System:**

If documents are required for exam, document type will be found in the SO60 Record ??

**FDA utilizes Import Trade Auxiliary Communication System (ITACS) for documents**

ITACS provides the import trade community with three functions:

- the ability to check on the status of an entry,
- the ability to submit entry documentation electronically
- the ability to submit goods availability information for targeted shipments electronically.

ITACS may be accessed at https://itacs.fda.gov[1] and the presentation provides an overview and walkthrough of ITACS functionality.

**Cargo Release Status Notifications:**

The Line with the most severe condition will reflect in the FDA overall status

| Entry Level Status Codes are: | |
|---|---|
| **Code** | **Description** |
| **01** | DATA UNDER PGA REVIEW |
| **02** | HOLD INTACT |
| **04** | DATA REJECTED PER PGA REVIEW |
| **06** | DO NOT DEVAN |
| **07** | MAY PROCEED |
| **08** | MOVE TO SECURE HLDNG FCLTY |
| **10** | DOCUMENTS REQUIRED |
| **11** | INTENSIVE - EXAM/SAMPLE |

| Entry Line Level Status Codes are: | |
|---|---|
| **Code** | **Description** |
| **01** | DATA UNDER PGA REVIEW |
| **02** | HOLD INTACT |
| **04** | DATA REJECTED PER PGA REVIEW |
| **07** | MAY PROCEED |

| PGA Line Level Status Codes are: | |
|---|---|
| **Code** | **Description** |
| **01** | DATA UNDER PGA REVIEW |
| **04** | DATA REJECTED PER PGA REVIEW |
| **07** | MAY PROCEED |

| If PGA Entry Level, PGA Entry Line Level or PGA Line Level Status Code is: | Then a Valid Status | Description |
|---|---|---|

| | Reason Code can be: | |
|---|---|---|
| 2 | 11 | HOLD INTACT |
| 2 | 12 | EXAM/SAMPLE |
| 2 | 25 | ADDITIONAL VERIFICATION NEEDED |
| 2 | 15 | DATA INACCURATE - CONTACT PGA |
| 4 | 14 | DATA REJECTED PER PGA REVIEW |
| 6 | 21 | EXAM DO NOT DEVAN |
| 7 | 22 | MAY PROCEED |
| 7 | 23 | RELEASED |
| 7 | 24 | RELEASED WITH COMMENTS |
| 10 | 90 | ADDITIONAL INFORMATION NEEDED |
| 11 | 34 | EXAM |

**For questions about FDA Medical Device Message Set**

## Points of Contact

If you have technical questions about the content of this Supplemental Guide, please email FDA at ACE_Support@fda.hhs.gov.

If you have other questions about this Guide or its data samples, please contact:

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**Medical Device Product Classification Database**

- This database includes:
  - list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.
  - **http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm**

**Firm's Registration and Listing Status**

- CDRH maintains a web site with establishment registration and listing data
  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
- This data is updated weekly
- This site does not give device listing numbers since this is proprietary information

**Medical Device Resources:**

Medical devices, March 24, 2011:

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm248321.htm

Medical and nonmedical radiation-emitting electronic products, September 6, 2011:
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm271180.htm

Device Advice: Comprehensive Regulatory Assistance

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

Establishment Registration & Device Listing

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Importing and Exporting Devices

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/default.htm

**FDA Supplemental Guide:**

The PGA Message Set chapter/implementation guide and its related Appendix PGA can be found on CBP.gov at:
http://www.cbp.gov/document/guidance/appendix-pga

The ACE ABI CATAIR – Custom and Trade Automated Interface Requirements:
http://www.cbp.gov/document/guidance/pga-message-set

Appendix V Government Agency Codes:
http://www.cbp.gov/document/guidance/appendix-v-government-agency-codes

Appendix R Intended Use Codes for ACE:
http://www.cbp.gov/document/guidance/appendix-r-intended-use-codes-ace

Appendix B Valid Codes:
http://www.cbp.gov/document/guidance/appendix-b-valid-codes

Appendix C:
http://www.cbp.gov/document/guidance/appendix-c-tariff-abbreviations