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

This document provides general technical guidance for persons importing Medical Devices on what declaration information to report via the Automated Commercial Environment (ACE). It is not intended to cover all specific scenarios. Please refer to the FDA Supplemental Guide to the CBP and Trade Automated Interface Requirements (CATAIR) for information on how to make electronic filings. The document is not an official statement of the Federal government and does not create any requirements; rather it explains what information to input in accordance with the CBP pilots for FDA Medical Devices.

Medical Devices

- 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. FDA's Center for Medical Devices and Radiological Heath regulates a range of products from microwaves to DVD drives.
- 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."

- Some non-medical purposes are also regulated as medical devices due to safety concerns.
- The intended use of a device or certain claims made on the labeling could also make it a medical device.

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

Description
Commercial Description
Government Agency Code (FDA)
Government Program Code (DEV)
Government Agency Processing Code (RED, NED)
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
Device Initial Importer 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 (If disclaiming, FDA does not require the above information)

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, Use only one of the following
Intended Use Description – i.e. Sample Devices, or Return Shipment, etc.

Intended Use (see PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional[1] Affirmations	Optional Affirmations
081.001	• Standard import of device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device	DEV, DFE, LST	DI, IRC, LWC, PM#	
081.002*	Import of a device for domestic refurbishing	DEV, DFE, LST	DI, IRC, LWC, PM#	
081.003	domestically manufactured device that is part of a medical device convenience kit	DDM, DFE, KIT, LST	DI, IRC, LWC, PM#	
081.004	foreign manufactured device that is Part of a medical device convenience kit	KIT, DEV, DFE, LST	PM#, DI, LWC;IRC	
081.005	Device constituent part for drug-device combination	DEV, DFE, LST	DA, IND	

	product .			
Intended Use (see PG01 for definitions)	**Import Scenarios**	**Mandatory Affirmations**	**Conditional[1] Affirmations**	**Optional Affirmations**
140.000	Import of a device for charity	DEV, DFE, LST	DI, IRC, LWC, PM#	
081.007	Component for further manufacturing into a finished medical device	CPT		LST, PM#
081.008	Device component for use in a drug-device combination product	CPT	DA, IND	
170.000	Repair of medical device and re-exportation	DDM, IFE	DFE, DI, LST, IRC, LWC, PM#	
180.010	Import of research or investigational use in vitro diagnostic device			
180.014*	• Import of a device for non-clinical use/bench testing • Import of device sample for customer evaluation			
180.015*	Import of a medical device for clinical investigational use	IDE		
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	DDM, LST	DFE, DI, IRC, LWC, PM#	
920.002	Import of device that is US goods returned for sale to a third party	DFE, DDM, LST	DI, IRC, LWC, PM#	
950.001*	Import of a single-use device for domestic reprocessing	DDM, LST	DFE, DI, IRC, LWC, PM#	
950.002*	Import of a multi-use device for domestic reprocessing		DDM, DFE, DI, IRC, LST, LWC, PM#	
970.000	Import for Export: • Import of a medical device for further processing and re-	DEV, DFE, IFE, LST		

	exportation • Importation of a medical device or accessory for further manufacturing into an export-only medical device			
970.001	Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	IFE, CPT, DDM, LST		
100.000*	• Device For Personal Use • •			
110.000*	• Public Exhibition/Trade Show			
940.000*	• Compassionate Use/Emergency device			
081.006	• Import under enforcement discretion provisions			

Product Code
Only one Product Code Number per product is allowed. For components, use the product code of the most likely device the component will be incorporated into if not known.

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)
http://www.cbp.gov/document/guidance/appendix-c-iso-country-codes

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

Entity Information:
Manufacturer of Goods (MF) – Medical Device
Manufacturer means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. **The term includes any person who either:**

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;

(3) Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or

(4) Is the U.S. agent of a foreign manufacturer.

Shipper (DEQ)

The FDA Shipper is the actual shipper of the product. This can typically be determined from the freight bill or bill of lading, etc. The FDA Shipper may be the same entity as the invoicing party.

FDA Importer (FD1)
Importer means, for purposes of this part, 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.

Device Initial Importers (DII)
The initial importer of the device must register its establishment with FDA. An initial importer is 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. Registration information can be found under Establishment Registration.
Initial importers are also subject to Medical Device Reporting (MDR) under 21 CFR 803, Reports of Corrections and Removals under 21 CFR 806, and Medical Device Tracking under 21 CFR 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.

Delivered To Party (DP)
Site where the goods are being delivered. It represents the facility to physically receive the goods after arrival in the US.

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

FDA requires Entity Name and Entity Address. Additionally, FDA/CDRH prefers to use FEI numbers for identifying the Entity; IF FEI is not available THEN DUNS.

Registration Number
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 provide a 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. Providing the broker's name and phone number will assist FDA in contacting the appropriate point of contact if there are any discrepancies with the line/entry.

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

Code	*Description*	*Qualifier*
PM#	Device Premarket Number • Premarket Approval (PMA) number (i.e. Pxxxxxx) • Device Premarket Notification Number (PMN) ((510(k)) (i.e. Kxxxxxx) PMN or PMA number database found at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm • Product Development Protocols (PDP) number • Humanitarian Device Exemption (HDE) number	Any of the following: P+6N; N+4N, 5N, or 6N; D+6N; H+6N; K+6N; DEN+6N
DDM	Device Domestic Manufacturer	1 - 10N
DEV	Device Foreign Manufacturer Registration Number 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
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) ▪ 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.) ▪ Note: Each shipment must have its own test results.	Indicator only
KIT	Device Imported Kit of Finished Device	Indicator

		only
LST	Device Listing Number 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 • This Code should be used when importing electrode lead wires, patient cables, or devices that use them. • The Affirmation indicates that the device does not contain any pre-wired electrodes, electrode lead wires, or patient (transducer) cables	Indicator Only

The table below shows which Affirmations of Compliance are Mandatory (M), Conditional (C) or Optional (O) based on the Intended Use Code/Import Scenario:

Intended Use (see PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional[1] Affirmations	Optional Affirmations
081.001	• Standard import of device, accessories, or components regulated as a finished device • Import of refurbished device • Import of a reprocessed device	DEV, DFE, LST	DI, IRC, LWC, PM#	
081.002*	Import of a device for domestic refurbishing	DEV, DFE, LST	DI, IRC, LWC, PM#	
081.003	domestically manufactured device that is part of a medical device convenience kit	DDM, DFE, KIT, LST	DI, IRC, LWC, PM#	
081.004	foreign manufactured device that is Part of a medical device convenience kit	KIT, DEV, DFE, LST	PM#, DI, LWC;IRC	
081.005	Device constituent part for drug-device combination product	DEV, DFE, LST	DA, IND	
140.000	Import of a device for charity	DEV, DFE, LST	DI, IRC, LWC, PM#	
155.010	Component for further manufacturing into a finished medical device	CPT		LST, PM#
155.011	Device component for use in a drug-device combination product	CPT	DA, IND	
170.000	Repair of medical device and re-exportation	DDM, IFE	DFE, DI, LST, IRC, LWC, PM#	
180.010	Import of research or investigational use in vitro diagnostic device			
180.100*	• Import of a device for non-clinical use/bench testing • Import of device sample for customer evaluation			
180.200*	Import of a medical device for clinical investigational use	IDE		
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	DDM, LST	DFE, DI, IRC, LWC, PM#	
920.002	Import of device that is US goods returned for sale to a third party	DFE, DDM, LST	DI, IRC, LWC, PM#	
950.001*	Import of a single-use device for domestic reprocessing	DDM, LST	DFE, DI, IRC, LWC, PM#	

950.002*	Import of a multi-use device for domestic reprocessing		DDM, DFE, DI, IRC, LST, LWC, PM#	
970.001	Import for Export: • Import of a medical device for further processing and re-exportation • Importation of a medical device or accessory for further manufacturing into an export-only medical device	DEV, DFE, IFE, LST		
970.002	Import for Export: • Importation of a medical device component for further manufacturing into an export-only medical device	IFE, CPT, DDM, LST		
110.000* 100.000* 940.000* 081.006	• Public Exhibition/Trade Show • Device For Personal Use • Compassionate Use/Emergency device • Import under enforcement discretion provisions			

¹: The conditional affirmations are required if applicable to the product being declared. For example, if the product requires premarket clearance (510(k)), then PM# must be provided.
*Annotates that additional information may be needed at time of entry in order for FDA to make a final admissibility decision.

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. **Pieces must be declared as the base unit.**

Valid FDA Units of Measure for Packaging Containers

Code	*Description*
CS	Case
CT	Carton
BX	Box
PK	Package

Valid FDA Units of Measure for the Base Unit (Last Quantity Transmitted)

Code	*Description*
PCS	Pieces (Count)

Anticipated Arrival Date, Time and Location

This is a mandatory PGA input record that provides data pertaining to the date, time and location (Anticipated Arrival Location Code is Optional) 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:
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 Reason Code can be:	Description
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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FDA Supplemental Guide:
http://www.cbp.gov/document/guidance/fda-supplemental-guide-release-16

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

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

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