



FDA Supplemental Guidance



Intended Use Code	Intended Use Definition	Relevant Medical Device Import Scenarios
081.001	For Human Medical Use as a Medical Device	<ul style="list-style-type: none"> <li>Standard Import of a medical device, accessories, or components regulated as a finished device</li> <li>Import of refurbished device</li> <li>Import of a reprocessed device</li> </ul>
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).	
081.006	Import of a medical device under enforcement discretion provisions per final guidance: <a href="http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm401996.pdf">http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm401996.pdf</a>	Applicable product codes for CBP business rule: 80O -- UG; 86N -- FF 86N -- FG; 80N -- XQ 90L -- MB; 90L -- MD
100.000	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	<ul style="list-style-type: none"> <li>Includes import of device for trade show</li> </ul>
140.000	For Charitable Organization Use as a Non-Food Product	
081.007	Component for further manufacturing into a finished medical device	
081.008	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	<ul style="list-style-type: none"> <li>Repair of medical device and re-exportation</li> </ul>
180.010	For Research and Development as a Non-Food Product - For research and development as a medical device	<ul style="list-style-type: none"> <li>Import of research or investigational use in vitro diagnostic device</li> </ul>
180.014	For Research and Development as a Non-Food Product – for bench testing or nonclinical research use	<ul style="list-style-type: none"> <li>Import of a device for non-clinical use/bench testing</li> <li>Import of device sample for customer evaluation</li> </ul>
180.015	For Research and Development as a Non-Food Product – import of a medical device for clinical investigational use	
920.001	Import of a device that is US goods returned for refund/overstock (to manufacturer)	<ul style="list-style-type: none"> <li>Refund/overstock</li> <li>Bench Testing</li> <li>Corrective Action Prevention Action (CAPA) Plan Investigation</li> <li>Recall</li> </ul>
920.002	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	<ul style="list-style-type: none"> <li>Import of a medical device for further processing and re-exportation</li> <li>Import of medical device or accessory for further manufacturing into an export only medical device</li> </ul>



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Intended Use Code	Intended Use Definition	Relevant Medical Device Import Scenarios
970.001	Import for Export	<ul style="list-style-type: none"><li>• Import of a medical device component for further manufacturing into an export only medical device</li></ul>



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Intended Use (see PG01 for definitions)	Import Scenarios	Mandatory Affirmations	Conditional <sup>1</sup> Affirmations	Optional Affirmations
081.001	<ul style="list-style-type: none"> <li>Standard Import of device, accessories, or components regulated as a finished device</li> <li>Import of refurbished device</li> <li>Import of a reprocessed device</li> </ul>	DEV, DFE, LST	IRC, LWC, PM#	DI
081.002*	Import of a device for domestic refurbishing	DEV, DFE, LST	IRC, LWC, PM#	DI
081.003	domestically manufactured device that is part of a medical device convenience kit	DDM, DFE, KIT, LST	IRC, LWC, PM#	DI
081.004	foreign manufactured device that is Part of a medical device convenience kit	KIT, DEV, DFE, LST	PM#, LWC;IRC	DI
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	IRC, LWC, PM#	DI
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, LST, IRC, LWC, PM#	DI
180.010	Import of research or investigational use in vitro diagnostic device			
180.014*	<ul style="list-style-type: none"> <li>Import of a device for non-clinical use/bench testing</li> <li>Import of device sample for customer evaluation</li> </ul>			
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, IRC, LWC, PM#	DI
920.002	Import of device that is US goods returned for sale to a third party	DFE, DDM, LST	IRC, LWC, PM#	DI
950.001*	Import of a single-use device for domestic reprocessing	DDM, LST	DFE, IRC, LWC, PM#	DI
950.002*	Import of a multi-use device for domestic reprocessing		DDM, DFE, IRC, LST, LWC, PM#	DI
970.000	Import for Export: <ul style="list-style-type: none"> <li>Import of a medical device for further processing and re-exportation</li> <li>Importation of a medical device or accessory for further manufacturing into an export-only medical device</li> </ul>	DEV, DFE, IFE, LST		
970.001	Import for Export: <ul style="list-style-type: none"> <li>Importation of a medical device component for further manufacturing into an export-only medical device</li> </ul>	IFE, CPT, DDM, LST		
100.000*	<ul style="list-style-type: none"> <li>Device For Personal Use</li> </ul>			
110.000*	<ul style="list-style-type: none"> <li>Public Exhibition/Trade Show</li> </ul>			
940.000*	<ul style="list-style-type: none"> <li>Compassionate Use/Emergency device</li> </ul>			
081.006	<ul style="list-style-type: none"> <li>Import under enforcement discretion provisions per final guidance</li> </ul>			