GHY International
GEO. H. YOUNG & CO. LTD. | GHY USA INC.

FDA Medical Devices

Account Number		Account Name	
DUNS Number *(if available)*		Client Part Number*	
Description of Product *(as complete as possible)*			
Government Agency Processing Code Select one		Tariff Number	
Country of Origin**	FDA Product Code *(if known)*	FDA Country of Production **	
Cargo Storage Status Select one	Intended Use of Product *NOTE: Conditional affirmations are required if applicable to the product being declared. Ex: If the product require premarket clearance 510k, the PM# must be provided* Select one		

** Part number as shown on Customs document to identify the product (item number, SKU, etc.)*
*** U.S. Customs considers the country of origin to be the country where the product last underwent a "substantial transformation" (resulting in an increase in value.) The FDA considers the country of origin to be that of the actual manufacturer. Actual manufacturer is defined as the last party involved in the production process.*

FDA Actual Manufacturer

Company Name			
Address		City	
State/Province	Zip/Postal Code	Country	DUNS Number *(if available)*

Manufacturer/Exporter Registration Numbers (Provide for all applicable)

PM#: Device premarket notification number 510K	DEV: Device foreign manufacturer registration number
LST: Device listing number for product	IDE: Investigational device exemption number
KIT: Device imported kit of finished device	DFE: Device foreign exporter registration number
PMA: Device premarket approval number	DDM: Domestic device manufacture
CDP: Device component (If component, no registration # required)	Other

FDA Shipper (As shown on Customs document, BOL or airway bill)

Company Name			
Address		City	
State/Province	Zip/Postal Code	Country	DUNS Number *(if available)*

FDA INTENDED USE

ACE INFORMATION SHEET

GHY USA needs to know, as your customs broker, how the FDA-regulated products being imported are intended to be used and/or why the products are being imported.

In order for us, here at GHY USA, to enter the appropriate end use code, as an importer you should confirm that your invoices clearly show what the end use is going to be for the product. Please refer to the below intended use descriptions required, to ensure your own descriptions are complete.

MEDICAL DEVICES

- 081.001 - For Human Medical use as a medical device (standard import of a medical device, accessories, or components) regulated as finished devices, import of refurbished device, import of a reprocessed device
- 081.002 - Refurbishing
- 081.003 - Domestically manufactured device that is part of a medical device convenience kit
- 081.004 - Foreign manufactured device that is part of a medical device convenience kit
- 081.005 - Device for use in a drug/device combination product
- 081.006 - Import of a medical device under enforcement discretion, applies to the following product codes: 80O--UG, 86N--FF, 86N--FG, 80N--XQ, 90L--MB, 90L--MD only
- 100.000 - Personal Use
- 110.000 - Public exhibition or taking orders (includes trade shows)
- 140.000 - Charitable organization use
- 081.007 - Component for further manufacturing into a finished medical device
- 081.008 - Device for use in a NDA/ANDA/BLA drug device combination product
- 170.000 - Repair
- 180.010 - Research & development as a medical device
- 180.014 - Research & development for bench testing or non-clinical research
- 180.015 - Research & development - clinical investigation use
- 920.001 - US manufactured medical device returned as over-stock, refund
- 920.002 - US manufactured device sale to a third party
- 940.000 - Compassionate use, emergency use device
- 950.001* - Single use device for domestic reprocessing
- 950.002* - Multi-use device for domestic reprocessing
- 970.000 - Import for export (must be further manufactured or processed, and then exported)- device or accessory
- 970.002 - Import for export (must be further manufactured or processed, and then exported)-component

  NOTE: Conditional affirmations are required if applicable to the product being declared, for example, if the product requires premarket clearance 510k, then PM# must be provided.
  * annotates that additional information may be needed at the time of entry in order for FDA to make a final admissibility decision.
- UNK - Unknown