FDA Product Data Sheet: 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)*