

PRODUCT MASTER DATA SPECIFICATION

1450J

Document Number:  
SPE003918

ECN #:  
ECN031719

Revision (letter):  
D

Master Data / GUDID Data Elements	MDM or SAP Value (Y/N)	LSP Upload Tool Value (Y/N)	Configuration	Configuration	Configuration
			001450J	011450J	**021450J
PRODUCT INFORMATION SECTION					
Packaging Assembly Number	No	No	N/A	1450J Rev 001	1450J Rev 001
Product Shelf Life (Months)	Yes	No	N/A	N/A	N/A
Maximum Sterilization Dose	No	No	N/A	N/A	N/A
Company Name	Yes	Yes	Megadyne Medical Products, Inc	Megadyne Medical Products, Inc	Megadyne Medical Products, Inc
Single Use Product?	Yes	Yes	No	No	No
Capital Indicator	Yes	No	Yes	Yes	Yes
Associated Product Code Indicator	Yes	No	No	No	No
Associated Product Code	No	No	N/A	N/A	N/A
Special Storage Requirement Code / Conditions:	Yes	Yes	N/A	N/A	N/A
Product SubType	Yes	No	Manufactured Finished Good	Manufactured Finished Good	Manufactured Finished Good
Is this product software?	Yes	No	No	No	No
Is product considered hazardous?	Yes	No	Not Hazardeous	Not Hazardeous	Not Hazardeous
Device Part Marking Required?	Yes	Yes	Yes	Yes	Yes
Device Part Marking Exemption Rationale (if "No" in Row 26)	Yes	Yes	NA	NA	NA

GTIN (Primary Device Identifier)	Yes	Yes	10614559105276	10614559105276	10614559105276
LABELING SECTION					
Device Description	No	Yes	Mega Power Bipolar Foot Pedal, Foot Switch, 12ft, for use with Mega Power generator	Mega Power Bipolar Foot Pedal, Foot Switch, 12ft, for use with Mega Power generator	Mega Power Bipolar Foot Pedal, Foot Switch, 12ft, for use with Mega Power generator
Device Labeled as "containing natural rubber latex or dry natural rubber"	Yes	Yes	No	No	No
Is the device labeled as "not made with natural rubber latex"?	No	Yes	No	No	No
Does this product have a clinically relevant size?	No	No	No	No	No
Clinically Relevant Size (free text):	No	Yes	N/A	N/A	N/A
What MRI Safety Information does the labeling contain?	Yes	Yes	Labeling does not contain MRI safety information	Labeling does not contain MRI safety information	Labeling does not contain MRI safety information
Brand Name	Yes	Yes	Megadyne	Megadyne	Megadyne
Product has special Storage and Handling Conditions?	No	Yes	Yes	Yes	Yes
Storage and Handling Type 1?	No	Yes	Storage Environment Temperature	Storage Environment Temperature	Storage Environment Temperature
Storage and Handling Low Value 1:	No	Yes	-40	-40	-40
Storage and Handling High Value 1:	No	Yes	70	70	70
Storage and Handling Unit 1:	No	Yes	Degrees Celsius	Degrees Celsius	Degrees Celsius
Storage and Handling Type 2?	No	Yes	Storage Environment Humidity	Storage Environment Humidity	Storage Environment Humidity
Storage and Handling Low Value 2:	No	Yes	15	15	15
Storage and Handling High Value 2:	No	Yes	95	95	95
Storage and Handling Unit 2:	No	Yes	Percent (%) Relative Humidity	Percent (%) Relative Humidity	Percent (%) Relative Humidity
Customer Contact Phone:	No	Yes	+18015769669	+18015769669	+18015769669
Customer Contact Email:	No	Yes	megadyne.udi@megadyne.com	megadyne.udi@megadyne.com	megadyne.udi@megadyne.com
PACKAGING SECTION					
Eaches per Box (device count)	Yes	No	1	1	1

Eaches per Case	Yes	No	10	N/A	N/A
Boxes per Case	Yes	No	5	N/A	N/A
Instrument Net Weight	Yes	No	N/A	N/A	N/A
**Number of Case Layers per Tote	No	No	N/A	N/A	N/A
**Total Number of Cases per Tote	No	No	N/A	N/A	N/A
Is an unpackaged GTIN required?	No	No	No	No	No
Unpackaged GTIN	No	Yes	N/A	N/A	N/A
Is product Lot or Serial Controlled?	Yes	No	Lot Controlled	Serial Controlled	Serial Controlled
Product is managed by a Date of Manufacture (DOM)?	No	Yes	Yes	Yes	Yes
Product is managed by the Expiration Date?	Yes	Yes	No	No	No
Product is managed by a Donation Identification Number?	No	Yes	No	No	No
Unit of Sale	Yes	No	Each	Each	Each
**Case Part Number	No	No	N/A	N/A	N/A
**Is Case Part Number New?	No	No	N/A	N/A	N/A
**Case / Pallet Configuration	No	No	N/A	N/A	N/A
**Dimensional Units of Measure (Inches / Pounds/ Grams per Cubic Centimeter)					
**Length (Each)	Yes	No	2	2	2
**Length (Box)	Yes	No	N/A	N/A	N/A
**Length (Case)	Yes	No	N/A	N/A	N/A
Width (Each)	Yes	No	11	11	11
Width (Box)	Yes	No	N/A	N/A	N/A
Width (Case)	Yes	No	N/A	N/A	N/A
Height (Each)	Yes	No	7.5	7.5	7.5

Height (Box)	Yes	No	N/A	N/A	N/A
Height (Case)	Yes	No	N/A	N/A	N/A
Weight (Each)	Yes	No	3.6	3.6	3.6
Weight (Box)	Yes	No	N/A	N/A	N/A
Weight (Case)	Yes	No	N/A	N/A	N/A
**Density (Box)	No	No	N/A	N/A	N/A
**Density (Case)	No	No	N/A	N/A	N/A
GTIN (Each)	Yes	Yes	10614559105276	10614559105276	10614559105276
GTIN (Box)	Yes	No	N/A	N/A	N/A
GTIN (Case)	Yes	No	N/A	N/A	N/A
Single Unit Replacement Information (Inches )					
Single Unit Replacement for this product?	Yes	No	N/A	N/A	N/A
Single Unit Replacement Product Code?	Yes	No	N/A	N/A	N/A
Single Unit Pack-Out Configuration?	Yes	No	N/A	N/A	N/A
Single Unit (Length)	Yes	No	N/A	N/A	N/A
Single Unit (Width)	Yes	No	N/A	N/A	N/A
Single Unit (Height)	Yes	No	N/A	N/A	N/A
Demonstration Unit Information (Inches)					
Is there a Demonstration Unit for this product?	Yes	No	N/A	N/A	N/A
Demonstration Unit Product Code	Yes	No	N/A	N/A	N/A
Demonstration Unit Pack-Out (Length)	Yes	No	N/A	N/A	N/A
Demonstration Unit Pack-Out (Width)	Yes	No	N/A	N/A	N/A
Demonstration Unit Pack-Out (Height)	Yes	No	N/A	N/A	N/A
STERILIZATION SECTION					

<b><i>Packaged as Sterile?</i></b>	Yes	Yes	No	No	No
Sterilization Method	Yes	No	N/A	N/A	N/A
Customer required to sterilize product prior to use?	No	No	No	No	No
Sterilization Method Prior to Use (customer)?	No	Yes	N/A	N/A	N/A
CONTRACT ADMINISTRATION SECTION					
Product Type	Yes	No	8	8	8
Contract Type	Yes	No	9	9	9
Franchise Price Group	Yes	No	ES38	ES38	ES38
DW Product Categorization	Yes	No	308 - Ultracision	308 - Ultracision	308 - Ultracision
PRICING SECTION					
Federal Schedule Supply Indicator	Yes	No	No	No	No
Product will require back pricing?	Yes	No	Yes	Yes	Yes
COMMERCIAL FINANCE SECTION					
Minor Product Group Name and Number	Yes	No	47110	47110	47110
Product Tax Group	Yes	No	B8	B8	B8
REGULATORY AFFAIRS SECTION					
<b><i>Product is a Kit?</i></b>	Yes	Yes	No	No	No
CE Mark?	Yes	No	Yes	Yes	Yes
<b><i>Combination Product?</i></b>	No	Yes	No	No	No
Prescription Status (Rx or OTC)?	No	Yes	Rx	Rx	Rx
Labeler Duns Number	No	Yes	185444825	185444825	185444825
Device Exempt from Pre-Market Submission?	No	Yes	No	No	No
FDA Pre-Market Authorization Number:	No	Yes	K050579	K050579	K050579

Supplement Number:	No	Yes	N/A	N/A	N/A
Human Cell, Tissue or Cellular Tissue Based Product (HCT/P)?	No	Yes	No	No	No
FDA Device Class:	No	Yes	II	II	II
FDA Product Code:	No	Yes	GEI	GEI	GEI
GMDN Code:	No	Yes	36336	36336	36336
FDA Listing Number	No	Yes	D009834	D009834	D009834
NEW PRODUCT & LIFECYCLE PLANNING SECTION					
Material Freight Group	Yes	No	804R	804R	804R
Country of Origin	Yes	No	USA	USA	USA
HTS Code	Yes	No	9018.90.6000	9018.90.6000	9018.90.6000