



ETHICON ENDO-SURGERY INC.
a Johnson & Johnson company

EPIcenter



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STRATEGY PLAN FORM

Introduction

Project Name	Update Megadyne Labeling per International Labeling Requirements (RA-DOC-016)
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Originated by: Dave Daniels / External Manufacturing Engineer	SEE EPI ESIG
	Date

Review / Approval	<div><div><u>Ricardo Rivera-Sanchez</u></div><div>Contract Account Manager (Supplier Relationship Manager)</div><div><u>SEE EPI ESIG</u></div><div>Date</div></div> <div><div><u>Kofi Baah</u></div><div>Engineering Manager (Technical Operations Manager)</div><div><u>SEE EPI ESIG</u></div><div>Date</div></div> <div><div><u>Kent Allen</u></div><div>EM Quality Manager</div><div><u>SEE EPI ESIG</u></div><div>Date</div></div>
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Revision	Summary
A	Original
B	Revised to close Cp0235. Deliverables added to the supporting files section.

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Scope

Project Scope	Megadyne product labeling is being updated to meet the international labeling requirements in order to distribute Megadyne product globally. These labeling changes will require a product mod code change from 00 to 01.
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Product Name and Codes	Refer to Attachment 1 – Megadyne Product Codes
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Product Category	The identified product code(s) are a Category <u>E</u> per CP0235 .
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Responsible Areas	The following functional areas have been identified as those responsible for deliverables:
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Functional Area	Strategy/Deliverable (Content or Reference)	Person Responsible
Life Cycle	2019-MKT-DCO-004	Brian Bertke
	– Mega 2000 Return Electrode (3151354)	
	– Mega 2000S Return Electrode (3151356)	
	– Mega 2000 Return Electrode (3151353)	
	– Mega 2000S Return Electrode (3151355)	
Life Cycle	2019-MKT-DCO-005	Brian Bertke
	– IFU Mega 2000 (3000325)	
Life Cycle	2019-MKT-DCO-029	Brian Bertke
	– Screen Artwork Mega 2000 (3900321)	
Life Cycle	2019-ENG-DCO-012	Brian Bertke
	– Mega 2000 Pad Top Assembly (0800)	
	– Mega 2000 Pad, Sample Top Assembly (0800S)	
	– Electron, Sub-Assembly Mega 2000 Pad (6010328)	
	– Mega Pad subassembly (6020334)	
Life Cycle	2019-MKT-DCO-009	Brian Bertke
	– Patient return electrode pad (3151381)	
	– Patient return electrode pad (3151382)	
	– Patient return electrode pad (3151383)	
	– Patient return electrode pad (3151384)	
	– Patient return electrode pad (3151385)	
	– Patient return electrode pad (3151386)	
	– Patient return electrode pad (3151387)	
	– Patient return electrode pad (3151388)	
Life Cycle	2019-MKT-DCO-011	Brian Bertke

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	- Patient return electrode pad (3000327)	
Life Cycle	2019-MKT-DCO-010	Brian Bertke
	- MEGA SOFT PAD (3900322)	
	- MEGA SOFT PAD DUAL CORD (3900323)	
	- TOP URETHANE SHEET, .003 THK (5350206)	
	- TOP URETHANE SHEET, .003 THK (5350207)	
Life Cycle	2019-ENG-DCO-042	Brian Bertke
	- Mega Soft Single Cord Pad Top Assembly (0830)	
	- Mega Soft Dual Cord Top Assembly (0835)	
	- Mega Soft Single Cord Pad Top Assembly (0830S)	
	- Mega Soft Dual cord - Sample Top Assembly (0835S)	
	- Sub assembly for 0830,0830S (6020335)	
	- Subassembly for 0835,0835S (6020336)	
Life Cycle	2019-MKT-DCO-012	Brian Bertke
	- Patient Return Electrode Pad (3151389)	
	- Patient Return Electrode Pad (3151390)	
	- Patient Return Electrode Pad (3151391)	
	- Patient Return Electrode Pad (3151392)	
Life Cycle	2019-MKT-DCO-014	Brian Bertke
	- Patient Return Electrode Pad (3000328)	
Life Cycle	2019-MKT-DCO-013	Brian Bertke
	- ARTWORK PEDIATRIC MEGA SOFT (3900326)	
Life Cycle	2019-ENG-DCO-017	Brian Bertke
	- Pediatric Mega Soft Pad Top Assembly (0840)	
	- Pediatric Mega Soft Sample Pad Top Assembly (0840S)	
	- Subassembly for 0840,0840S (6020337)	
Life Cycle	2019-MKT-DCO-015	Brian Bertke
	- Patient Return Electrode Pad (3151393)	
	- Patient Return Electrode Pad (3151394)	
	- Patient Return Electrode Pad (3151395)	
	- Patient Return Electrode Pad (3151396)	
	- Patient Return Electrode Pad (3151397)	
	- Patient Return Electrode Pad (3151398)	
	- Patient Return Electrode Pad (3151399)	
	- Patient Return Electrode Pad (3151400)	
Life Cycle	2019-MKT-DCO-017	Brian Bertke
	- Patient Return Electrode Pad IFU (3000329)	
Life Cycle	2019-MKT-DCO-016	Brian Bertke
	- ARTWORK, UNIVERSAL MEGA SOFT PAD (3900327)	
	- ARTWORK, DUAL CORNER UNIVERSAL MEGA SOFT PAD (3900328)	
	- TOP AND BOTTOM URETHANE SHEET, UNIVERSAL MEGA SOFT (5350208)	
	- TOP AND BOTTOM MEGA SOFT URETHANE SHEET, DUAL CORNER UNIVERSAL (5350209)	
Life Cycle	2019-ENG-DCO-018	Brian Bertke
	- Universal Mega Soft (0845)	
	- Universal Dual Mega Soft (0846)	
	- Universal Mega Soft Sample Pad, Top Assembly (0845S)	
	- Universal Dual Mega Soft, Sample (0846S)	
	- Subassembly for 0845,0845S (6020338)	
	- Subassembly for 0846,0846S (6020339)	
Life Cycle	2019-MKT-DCO-041	Brian Bertke

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	- ACE700 Zip Pencil (3900336)	
	- ACE700 Zip Pencil (3900337)	
	- ACE700 Zip Pencil (3900338)	
	- ACE700 Zip Pencil (3900339)	
	- ACE700 Pencil (3151456)	
	- ACE700 Zip Pencil (3151457)	
	- ACE700 Zip Pencil (3151458)	
	- ACE700 Zip Pencil (3151459)	
	- ACE700 Zip Pencil (3151462)	
	- ACE700 Zip Pencil (3151463)	
Life Cycle	2019-MKT-DCO-042	Brian Bertke
	- IFU Zip Pen (3000336)	
	- IFU ACE Blade Electrodes (3000337)	
Life Cycle	2019-MKT-DCO-043	Brian Bertke
	- Artwork, Shipper Box, Zip pen (3900340)	
Life Cycle	2019-ENG-DCO-067	Brian Bertke
	- ACE BLADE 700, 2.5", ZIP PEN, "C" CONNECTOR, 10 FT. TUBING (ME7251C)	
	- ACE BLADE 700, 2.5", ZIP PEN, EC CONNECTOR, 10 FT. TUBING (ME7251E)	
	- ACE BLADE 700, 2.5", MODIFIED, ZIP PEN, "C" CONNECTOR, 10 FT. TUBING (ME725M1C)	
	- ACE BLADE 700, 2.5", MODIFIED, ZIP PEN, EC CONNECTOR, 10 FT. TUBING (ME725M1E)	
Life Cycle	2019-MKT-DCO-123	Brian Bertke
	- ACE700 Translation (3151721)	

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ATTACHMENT 1

Megadyne Product Codes

<u>Product Codes (12)</u>	<u>Description</u>
0800	Mega 2000 Pad
0800S	Mega 2000 Pad, Sample
0830	Mega Soft Single Cord Pad
0835	Mega Soft Dual Cord Pad
0830S	Mega Soft Single Cord Pad, Sample
0835S	Mega Soft Dual Cord Pad, Sample
0840	Pediatric Mega Soft Pad
0840S	Pediatric Mega Soft Pad, Sample
0845	Universal Mega Soft Pad
0846	Universal Dual Mega Soft Pad
0845S	Universal Mega Soft Pad, Sample
0846S	Universal Dual Mega Soft Pad, Sample