K080741

Section 5 510(k) Summary

December 15, 2008

DEC 16 2008

A. Submitter's Name / Address

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B. Contact Person

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C. Megadyne's Manufacturing Facility

Megadyne Medical Products, Inc.
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D. Device Name

Common Name:	Device, electrosurgical, cutting & coagulation & accessories
Trade Name:	Mega Soft Patient Return Electrode
Classification (if known):	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories

E. Predicate Devices

The predicate devices include:

Megadyne's Mega 2000™ Soft Patient Return Electrode Pad which was cleared for marketing via 510(k) # K021077 by FDA's Office of Device Evaluation on April 17, 2002;

Megadyne's Mega 2000™ Soft Dual Cord Patient Return Electrode Pad which was cleared for marketing via 510(k) # K031285 by FDA's Office of Device Evaluation on May 19, 2003;

Valleylabs E7512 Neonatal REM Polyhesive II Patient Return which was cleared for marketing via 510(k) #K994428 by FDA's Office of Device Evaluation on March 7, 2000; and

Leonard Lang's Skintact® Cool Contact Electrosurgical Grounding Plates with NH 04 gel which was cleared for marketing via 510(k) # K063161 by FDA's Office of Device Evaluation on November 26, 2006.

F. Applicant Device Description

The Mega Soft Patient Return Electrode is constructed of a layer of conductive material strain-relieved with two sheets of urethane material, and sealed between two asymmetric layers of a viscoelastic polymer called Akton®. (The top layer of polymer is thinner than the bottom layer.) The Akton polymer is encapsulated by a layer of urethane film. One or two two-conductor cables connects the conductive layer of the device to a two conductor DetachaCable™. The DetachaCable is connected to a standard monopolar electrosurgical unit (ESU). The device cable is insulated, strain-relieved, and connected well inside the device to prevent patient or user burns. In use, this device will lay on the operating surface with the patient lying on top, on the side labeled "patient side".

The adult-size device is large enough to extend at least the length and width of a typical patient torso. Pad size is approximately 20" x 46" x ½". The pediatric-size device is approximately 12" x 26" x ½" and is intended for pediatric patients weighing between 0.8 and 50 lbs.

G. Applicant Device Intended Use

The intended use of the Mega Soft Patient Return Electrode is to conduct monopolar electrosurgical energy from target tissue of a patient back to an electrosurgical unit (ESU), or generator. At the same time, the product reduces the risk of pressure related injury due to immobility during surgery.

This device is intended to be used whenever monopolar electrosurgy is indicated. Electrosurgical use is restricted to use with isolated monopolar electrosurgical generators. The device is not indicated for RF ablation.

H. Technological Characteristics

The proposed device shares the same technological characteristics found in the Megadyne predicate devices.

I. Safety information

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other patient return electrodes on the market. There are no new technologies incorporated into the device.

Megadyne has conducted extensive testing to ensure conformance to the voluntary standard ISO 60601-2-2:2006, *Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment,* and ANSI / AAMI HF 18-2001, *Electrosurgical Devices.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2008

Megadyne Medical Products, Inc.
% Ms. Ronda K. Magneson
Director, Regulatory Affairs
11506 South State Street
Draper, Utah 84020

Re: K080741
Trade/Device Name: Mega Soft® Reusable Patient Return Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 10, 2008
Received: December 12, 2008

Dear Ms. Magneson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K080741

Device Name: Mega Soft® Reusable Patient Return Electrode

Indications for use:

This device is designed to be used whenever monopolar electrosurgy is indicated. The intended use of this device is to conduct monopolar electrosurgical energy from target tissue of a patient back to one or two electrosurgical units (ESU), or generators. At the same time the product reduces the risk of pressure related injury due to immobility during surgery.

Electrosurgical use is restricted to use with isolated monopolar electrosurgical generators. The device is not intended for RF ablation.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080741

Prescription Use √ OR Over-The-Counter Use____

(Per 21 CFR 801.109)