

JAN 24 2014

**Section 4 510(k) Summary**

December 4, 2013

**A. Submitter's Name / Address**

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**C. Megadyne's Manufacturing Facility**

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**D. Device Name**

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

***E. Predicate Devices***

The predicate device is Megadyne's Mega Soft Return Electrode Pad which was cleared for marketing via 510(k) # K080741 by FDA's Office of Device Evaluation on December 12, 2008

***F. Applicant Device Description***

The MegaSoft Universal Patient Return Electrode is constructed of a layer of conductive material strain-relieved with two sheets of urethane material, and sealed between two symmetric layers of a viscoelastic polymer called Akton<sup>®</sup>. The Akton polymer is encapsulated by a layer of urethane film. One two-conductor cable connects the conductive layer of the device to a two conductor DetachaCable<sup>™</sup>. 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 either side of the pad.

The pad size is approximately 36" x 20" x 0.135" and is intended for patients weighing  $\geq 0.8$  lb. (350 grams).

***G. Applicant Device Intended Use***

The intended use of the MegaSoft Universal Patient Return Electrode is to conduct monopolar electrosurgical energy from target tissue of a patient back to an electrosurgical unit (ESU), or generator.

This device is intended to be used whenever monopolar electrosurgery is indicated. Electrosurgical use is restricted to use with isolated monopolar electrosurgical generators.

***H. Technological Characteristics***

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

***I. Safety information***

The only current flow from the patient to the MegaSoft Universal Patient Return Electrode Pad is via capacitive coupling. This device is designed to be current limiting ( $<100$  mA/cm<sup>2</sup>) to prevent the patient from getting return electrode site burns.

The Akton is used as a dielectric layer. The desirable attribute of this polymer is that it compresses but does not laterally move under pressure, thus maintaining dielectric protection.

Questions of safety and effectiveness are the same for this device as they are for the predicate device 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 following voluntary standards:

*IEC 60601-1:2005, Medical electrical equipment, Part 1: General requirements for safety and essential performance*

*IEC 60601-2-2:2009, Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment*



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Megadyne Medical Products Incorporated  
Ms. Ronda K. Magneson  
Director of Regulatory Affairs  
11506 South State Street  
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January 24, 2014

Re: K133726

Trade/Device Name: MegaSoft Universal® Patient Return Electrode  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation  
device and accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: December 26, 2013  
Received: December 27, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joshua C. Nipper -S**

Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Acting Director

For Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Section 3 Indications for Use Statement**

510(k) Number (if known):           K133726          

Device Name:           MegaSoft Universal® Patient Return Electrode          

Indications for use:

This device is designed to be used whenever monopolar electrosurgery 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.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

<b>DSD—DIVISION SIGN-OFF</b> Division of Surgical Devices <b>K133726</b> 510(k) Number:	<b>Long H. Chen -A</b>	Digitally signed by Long H. Chen -A DN: cn=US, ou=U.S. Government, o=FDA, ou=FDA, ou=People, cn=Long H. Chen -A, c=US, email=long.h.chen@FDA.gov, serial=19200300.100.1.1=130036 9056 Date: 2014.01.23 08:43:33 -0500
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for BSA

Prescription Use   X   OR Over-The-Counter Use             
(Per 21 CFR 801.109)