

K072559

**Section 5 510(k) Summary**

September 6, 2007

Page 1 of 2

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

Ronda K. Magneson  
Director, Regulatory Affairs and Quality Assurance  
Megadyne Medical Products, Inc.  
11506 South State Street  
Draper, UT 84020  
(801) 576-9669  
(801) 576-9698 fax

OCT 5 2007

**B. Contact Person**

Primary: Ronda K. Magneson  
Director of Regulatory Affairs / Quality Assurance  
Megadyne Medical Products, Inc.  
11506 South State Street  
Draper, UT 84020  
(801) 576-9669  
(801) 576-9698 fax

Alternate: Ihsan Samara  
Quality Manager  
Megadyne Medical Products, Inc.  
11506 South State Street  
Draper, UT 84020  
(801) 576-9669  
(801) 576-9698 fax

**C. Megadyne's Manufacturing Facility**

Megadyne Medical Products, Inc.  
11506 South State Street  
Draper, UT 84020  
(801) 576-9669  
(801) 576-9698 fax

K072559

Page 2 of 2

**D. Device Name**

Common Name: Device, electrosurgical, cutting & coagulation & accessories

Trade Name: Suction Coagulator

Classification (if known): 21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories

**E. Predicate Devices**

The predicate devices include the MegaDyne Suction Coagulator which was cleared for marketing via 510(k) # K946327 by FDA's Office of Device Evaluation on June-7, 1995; and Valleylab's LECTROVAC which was cleared for marketing via 510(k) #K791752 on October 4, 1979.

**F. Applicant Device Description**

The suction coagulator is a hand held electrosurgical device used for coagulation and aspiration during electrosurgical procedures. The device is available in two different configurations: hand controlled and foot controlled models. Both models are supplied with holsters.

**G. Applicant Device Intended Use**

The intended use of this device is to conduct monopolar electrosurgical energy from an electrosurgical generator (ESU) to target tissue during ENT and general surgical procedures. It is also a suction apparatus and is intended to be used to remove surgical smoke and fluids from the site. The device is intended for single use; it is not intended to be cleaned or reused.

**H. Technological Characteristics**

The proposed device shares the same technological characteristics found in the predicate devices. It is a handheld electrosurgical device used for coagulation and aspiration during electrosurgical procedures.

**I. Safety information**

Questions of safety and effectiveness are the same for this device as they are for the predicate devices and other suction coagulators 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*.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

OCT 5 2007

Re: K072559

Trade/Device Name: Suction Coagulator  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: September 06, 2007  
Received: September 11, 2007

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.

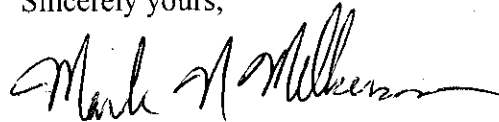
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms. Ronda K. Magneson

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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): K072559

Device Name: Suction Coagulator

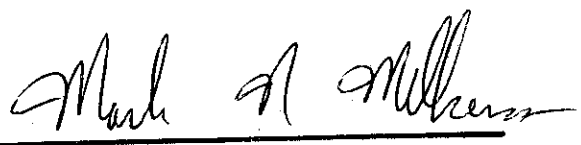
**Indications for use:**

The intended use of this device is to conduct monopolar electrosurgical energy from an electrosurgical generator (ESU) to target tissue during ENT and general surgical procedures. It is also a suction apparatus and is intended to be used to remove surgical smoke and fluids from the site. This device is intended to be used whenever monopolar electrosurgical coagulation and fluid aspiration are indicated.

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
**(Division Sign-Off)**  
**Division of General, Restorative,**  
**and Neurological Devices**  
510(k) Number K072559