K072559

Section 5 510(k) Summary

Page 1 of 9

September 6, 2007

A. Submitter's Name / Address

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OCT 5 2007

B. Contact Person

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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 electrosugical energy from an electrosugical 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.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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 ˇ 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.

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 electrosugical energy from an electrosugical 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 X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Milhern

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

510(k) Number K072559