MAR 2 4 2005

Section XV 510(k) Summary

K050579

February 9, 2005

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A. *Submitter's Name / Address*

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D. Device Name

Common Name:	Device, electrosurgical, cutting & coagulation & accessories
Trade Name:	MEGA Power
Classification (if known):	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories

E. Predicate Device

Valleylab Force FXc (K944602).

F. Applicant Device Description

The Megadyne MEGA Power Electrosurgical Generator is a microprocessor controlled, isolated output, high frequency generator designed for use in cutting and coagulating of tissue. The Generator has the ability to perform both monopolar cutting and coagulation and bipolar coagulation of tissue in a wide range of surgical applications.

G. Applicant Device Intended Use

General-purpose electrosurgical generator designed to produce radio frequency (RF) current for cutting and coagulation to be delivered to target tissue through an accessory electrode during open and laparoscopic surgical procedures.

H. Technological Characteristics

The operating principle of the proposed device is identical to the predicate device.

The proposed device conforms to the applicable sections of AAMI HF 18:2001, IEC 60601-1:2003 IEC 60601-2-2:1998 and IEC 60601-1-2:2001.

I. Safety information

Questions of safety and effectiveness are the same for this device as they are for the other electrosurgical generators on the market.

The proposed device conforms to the applicable sections of AAMI HF 18:2001, IEC 60601-1:2003 IEC 60601-2-2:1998 and IEC 60601-1-2:2001.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2005

Megadyne Medical Products, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K050579
Trade/Device Name: MEGA Power™
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 3, 2005
Received: March 7, 2005

Dear Mr. Job:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section IV Indications for Use Statement

510(k) Number (if known): K050579

Device Name: MEGA Power™

Indications for use:

General-purpose electrosurgical generator designed to produce radio frequency (RF) current for cutting and coagulation to be delivered to target tissue through an accessory electrode during open and laparoscopic surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)