



510(k) Summary

K 972273

June 17, 1997

Submitter's Name/Address:

JUL - 8 1997

John W. Smith
Director of Regulatory Affairs / Quality Assurance
MegaDyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

Contact Person:

Same as above

Device Name:

Common Name: Electrode, Electrosurgical, Patient Return
Trade Name: Undetermined
Classification (if known): 878.4400

Predicate Device:

PolyHesive patient return electrode, manufactured by Valleylab (K822572)

Device Description:

The MegaDyne reusable patient return electrode is constructed of a layer of conductive material, laminated between two sheets of dielectric plastic material. An insulated and strain-relieved two conductor cable connects the device to a standard monopolar electrosurgical unit (ESU). The capacitive patient return electrode is large enough to extend at least half the length and the full width of a typical patient torso. Sizes for both adult and pediatric patients are available.

This device is not intended to be attached to the patient. In typical use, this device will lay on an operating room table with the patient laying on top, on the side labeled "patient side".

MEGADYNE MEDICAL
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A disposable plastic sheath is placed over the device, which is replaced after each procedure, to allow for easy clean up between patients and to provide a second layer of dielectric protection.

A test wand is available as an accessory. The test wand is intended to be used for periodic electrode inspections. The test wand identifies electrical deficiencies in the return electrode outer dielectric layer.

Device Intended Use:

This device is intended to be used as a general purpose reusable patient return electrode for any standard ESU.

Safety information:

The only current flow from the patient to the return electrode is via capacitive coupling, through the patient-side dielectric plastic sheet. This current density is designed to be less than 100 mA per square inch at an ESU output of 700 mA rms. This low current density prevents the patient from getting return electrode site burns.

The large contact area between the electrode and the patient allows for enough current flow for electrosurgery to be performed at the surgical site.

This device conforms with the applicable sections of AAMI HF-18/1993.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John W. Smith
Director of Regulatory Affairs and
Quality Assurance
MegaDyne Medical Products, Inc.
11506 South State Street
Draper, Utah 84020

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Re: K972273
Patient Return Electrode
Disposable Electrode Sheath
Test Wand
Regulatory Class: II
Product Code: GEI
Dated: June 17, 1997
Received: June 18, 1997

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the devices, 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.

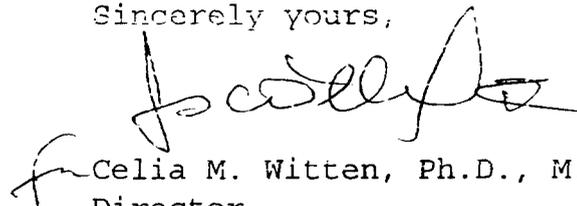
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical

Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

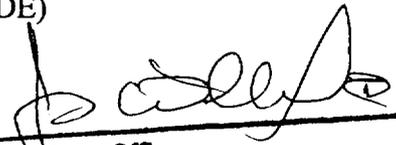
510(k) Number (if known): K972273

Device Name: MegaDyne reusable patient return electrode

Indications for use:

The MegaDyne reusable patient return electrode is to be used as a general purpose return electrode in any electrosurgical application in which a standard monopolar electrosurgical generator is used.

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972273

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use