NOV 6 1998

Section XIV 510(k) Summary K982826

August 6, 1998

A. Sponsor's Name/Address

Matt Sansom
Executive VP / COO
MegaDyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

B. Contact Person

John W. Smith
Regulatory Consultant
328 M Street
Salt Lake City, UT 84103
(801) 532-3334

C. Device Name

Common Name:	Electrode, Electrosurgical, Patient Return
Trade Name:	Mega 2000™
Classification	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories

D. Predicate Device

Reusable Patient Return Electrode, manufactured by MegaDyne. (K972273)

E. Applicant Device Description

The MegaDyne Mega 2000™ reusable patient return electrode is constructed of a layer of conductive material, laminated between two sheets of dielectric plastic material. A two conductor cable to connect the device to a standard monopolar electrosurgical unit (ESU) is connected to the conductive layer of the electrode. This cable is insulated and strain-relieved well inside the device to prevent possible patient or user burns.

The electrode is approximately 20" x 36". This size is large enough to extend at least half the length and full width of the typical patient torso. The device is not intended to be attached to the patient.

A clear plastic sheath is placed over the device. This sheath, which is replaced at a minimum each day, provides a second layer of dielectric protection.

The proposed device consists of the same device cleared in K972273, with some minor changes:

- The electrode sheath is no longer a single-use item. The sheath is to be replaced on at least a daily basis (as a maximum interval between changes).
- Conformance to the minimum capacitance requirement of the ANSI / AAMI HF 18 standard is no longer claimed.

F. Applicant Device Intended Use

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

G. Technological Characteristics

The technological characteristics of the proposed device are identical to the predicate device.

H. Safety Information

The only current flow from the patient to the return electrode is via capacitive coupling, through the patient side of the electrode and the plastic sheath. The current density of this capacitively-coupled current flow is design 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 capacitive contact area between the electrode and the patient allows for enough current flow for electrosurgery to be performed at the surgical site.

With the exception of the requirement for minimum capacitance, the device conforms with all applicable sections of ANSI / AAMI HF 18-1993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

MegaDyne Medical Products, Inc.
c/o Mr. John W. Smith
Regulatory Consultant
328 M Street
Salt Lake City, Utah 84103

Re: K982826
Trade Name: Mega 2000™
Regulatory Class: II
Product Code: GEI
Dated: August 06, 1998
Received: August 11, 1998

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is 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 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.

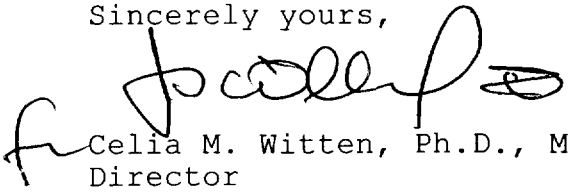
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 device 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 device as described in your 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 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 device, 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

Section IV Indications for Use Statement

510(k) Number (if known): K982826

Device Name: Mega 2000™

Indications for use:

The MegaDyne Mega 2000™ 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 K982826

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