



Applicant Device Intended Use:

This device is intended to be used in any application which requires electrosurgical cutting or coagulation.

Technological Characteristics:

<u>Component/ Feature</u>	MegaDyne's Electrosurgical Electrode	Predicate Device: Electrosurgical Blade (K861495)
Intended use	to be used in any application which requires electrosurgical cutting or coagulation	same
Electrode Material	300 series stainless steel	same
Insulation Material	Polyolefin	unknown
Configurations available	Blade, needle, and ball end electrode	same
Compatibility	Standard 3/32" shaft	same
Single use	yes	same
Conforms with ANSI / AAMI HF 18 - 1993	yes	unknown

Performance Data:

The Electrosurgical Electrode conforms with the relevant clause of ANSI / AAMI HF18 - 1993: 4.3.5.4, *Dielectric withstand of accessories.*



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

NOV - 7 1997

Re: K973346
Trade Name: Electrosurgical Electrode
Regulatory Class: II
Product Code: GEI
Dated: September 3, 1997
Received: September 5, 1997

Dear Mr. Smith:

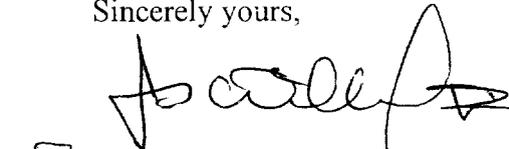
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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): K973342

Device Name: Electrosurgical Electrode

Indications for use:

The MegaDyne uncoated electrode is indicated for use in any surgical procedure which requires electrosurgical cutting and/or coagulation.

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973346

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use