K95-12

510(k) SUMMARY

APR - 7 1995

SAFETY AND EFFECTIVENESS SUMMARY

This information of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name/Address:

Drew D. Weaver
Director of Regulatory Affairs
MegaDyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
(801) 576-9698 fax

Contact Person:

Same as above

Date Summary Prepared:

March 2, 1995

Device Name:

Common Name:	Bipolar Forceps
Trade Name:	Not yet determined
Classification (if known):	Electrosurgical Cutting and Coagulation Device and Accessories, 79 GEI, 21 CFR 878.4400

MEGADYNE MEDICAL
PRODUCTS, INC.
11506 South State Street
Draper, Utah 84020
Phone (801) 576-9669
FAX (801) 576-9698
Toll Free (800) 747-6110

Predicate Devices:

Richard Wolf, Karl Storz, Apple Medical, Linvatec, MegaDyne Medical

Applicant Device Description:

This device is a bipolar electrosurgical device that is sold as a single use, disposable item. It is used in a forceps handle. A non-stick coating is used on the distal tines.

Applicant Device Intended Use:

This device is used in cases where bipolar electrosurgery is employed. No changes in safety or effectiveness are present.

Technological Characteristics:

The design is similar to the predicate devices. The materials are used in previously marketed devices or have passed the Tripartite battery of tests.

No new technology is employed so there are no new questions about this device in relation to the predicate devices.

Performance Data:

This device complies with the AAMI electrosurgical standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Drew D. Weaver
Director of Regulatory Affairs
MegaDyne Medical Products, Inc.
11506 South State Street
Draper, Utah 84020

Re: K951035
Bipolar Forceps
Regulatory Class: II
Product Code: GEI
Dated: March 2, 1995
Received: March 6, 1995

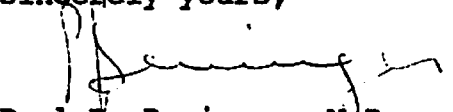
Dear Mr. Weaver:

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 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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP 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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Paul H. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

2