

K040699

Decision-Making Process Flowchart step	Answer	Remarks
Performance data demonstrate equivalence?	Yes	Performance data demonstrate substantial equivalence. <u>The changes do not affect the safety and effectiveness of the device.</u> Ref. Section VIII Performance Data and Standards Conformance.
“Substantially Equivalent” Determination		The device is <u>substantially equivalent</u> to the predicate devices.

Section XIV 510(k) Summary

March 12, 2004

A. Submitter's Name / Address

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 Megadyne Medical Products, Inc.
 11506 South State Street
 Draper, UT 84020
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B. Contact Person

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C. Device Name

Common Name: Device, electrosurgical, cutting & coagulation & accessories
Trade Name: Laparoscopic Electrode, Reusable Indicator Shaft (LERIS)
Classification (if known): 21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories

D. Predicate Devices

Megadyne's *E-Z Clean Laparoscopic Electrode*, cleared for marketing via 510(k) #(K913281) and, *Electrosurgical Cutting and Coagulation Device*, cleared for marketing via 510(k) #K943055.

E. Applicant Device Description

The Reusable Uncoated Laparoscopic Electrodes are stainless steel electrosurgical electrodes insulated over the majority of their length to protect against unwanted current paths. The insulation has a patented indication layer that aids in determining the electrode's end-of-life. The reusable uncoated laparoscopic electrode tip has the intended geometry for cutting and coagulation and is offered in several configurations. The electrodes are intended for general laparoscopic electrosurgical use, and designed to fit into industry standard electrosurgical pencils and/or foot cables distributed by various manufacturers.

F. Applicant Device Intended Use

Reusable Uncoated Laparoscopic Electrodes are intended to be used in general laparoscopic surgical procedures requiring the use of electrosurgical cutting and/or coagulation.
The electrodes are reusable; they are intended to be cleaned, sterilized, and reused.

G. Technological Characteristics

The Reusable Uncoated Laparoscopic Electrode shares the same technological characteristic found in the predicate devices. It is an electrode provided with various uncoated tip configurations and a shaft that includes the patented indicator shaft technology. The indicator shaft provides a safe method to utilize the electrode without compromising safety. This is accomplished by exposing a visible yellow layer indicating that the primary insulation has reached the end of its life.

H. Safety information

Questions of safety and effectiveness are the same for this device as for other laparoscopic electrodes on the market. There are no new technologies incorporated into the proposed electrode.

Prior to release of the device for distribution, Megadyne conducted extensive testing of the device to assure its conformance to the voluntary standard ANSI / AAMI HF 18-2001, *Electrosurgical Devices* (Ref. Appendix). The clauses of the standard which apply to accessories are:

Sterilization of reusable accessories:

Conformance with the sterilization of reusable accessories requirement was demonstrated using the methods specified by the standard. The device is well within the requirements of the standard.

Dielectric withstand of accessories:

Conformance with the dielectric withstand of accessories requirement was demonstrated using the method specified by the standard. The device is well within the requirements of the standard.

Shipping temperature:

Conformance with the shipping temperature requirement for accessories was demonstrated using the method specified by the standard. The device is well within the requirements of the standard.

Mechanical shock:

Conformance with the sterilization of reusable accessories requirement was demonstrated using the method specified by the standard. The device is well within the requirements of the standard.

I. Megadyne's Manufacturing Facility

Megadyne Medical Products, Inc.
11506 South State Street
Draper, UT 84020
(801) 576-9669
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Section XV Appendix

The following test reports are available upon request:

<u>Document Title</u>	<u>Document Number</u>
LERIS Dielectric Withstand Test	X1150198-01
LERIS Functionality Testing	X1150209-01
LERIS Electrode Environmental Cycling	Memo to Design History File
LERIS Mechanical Strength Test	X1150197-01



JUN - 4 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Ronda K. Magneson
Manager, Regulatory Affairs
and Quality Assurance
Megadyne Medical Products, Inc.
11506 South State Street
Draper, Utah 84020

Re: K040699

Trade/Device Name: Laparoscopic Electrode, Reusable Indicator Shaft (LERIS)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 12, 2004
Received: March 17, 2004

Dear Ms. Magneson:

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.

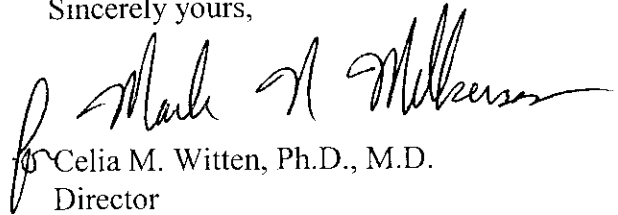
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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 (301) 594-4659. 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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal flourish at the end.

Celia M. Witten, Ph.D., M.D.

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): K040699

Device Name: Laparoscopic Electrode, Reusable Indicator Shaft (LERIS)

Indications for use:

The Reusable Laparoscopic Electrodes are intended to be used in general laparoscopic surgical procedures requiring the use of electrosurgical cutting and/or coagulation. The electrodes are reusable; they are intended to be cleaned, sterilized, and reused.

Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Williams

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

Megadyne Medical Products, Inc.

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