OCT 27 1997

ITI Medical Technologies, Inc.
2452 Armstrong Street
Livermore, CA 94550
(510) 371-8305
FAX (510) 371-8222

K973234

SUMMARY OF SAFETY AND EFFECTIVENESS

August 25, 1997

Contact Person: Roger W. Werne, Ph.D., President

Common or Usual Name: Electrosurgical Electrode

Proprietary Name: Midas Touch™ Electrosurgical Electrodes

Classification Name: Unit, Electrosurgical and Coagulation with accessories
21 CFR § 878.4400

Class and Panel: Regulatory Class II
Product Code: GEI General and Plastic Surgery 79

Predicate Devices:

MegaDyne Medical Products, Inc.	K903302
Aaron Medical Industries, Inc.	K913623

Description of Device: The ITI Medical Technologies, Inc. Midas Touch™ Electrosurgical Electrodes are similar in design to the predicate devices. They weigh about 2 grams, and have an industry standard 0.0937-inch (2.38 mm) diameter x 0.825-inch (22.22 mm) connector pin, with various tip lengths and configurations. They are made from a stainless steel metal alloy. Some models are available with a stick resistant coating. The transition point between the shaft and the tip has a protective plastic insulator sheath. Electrodes are packaged individually in sealed pouches, sold sterile, and intended for single use.

Statement of intended use: The ITI Medical Technologies, Inc. Midas Touch™ Electrosurgical Electrodes are intended for use in standard electrosurgical chucks and pencil type accessories wherever standard monopolar electrosurgical cutting and coagulation blade electrodes are used.

The intended use is identical to that of the predicate devices, i.e. a standard electrosurgical electrode to be used with most standard electrosurgical chucks and pencils by a trained medical practitioner. There are no differences in the devices concerning intended use or the safety or effectiveness when used as labeled.

Statement of technological characteristics:

The ITI Medical Technologies, Inc. Midas Touch™ Electrosurgical Electrodes incorporate no significant change in design, materials, energy source or other technological characteristics than those found in the predicate devices. Their form factors are similar to the predicate devices. They can be used with the same standard Electrosurgical units and accessories as the predicate devices.

The only difference between the Midas Touch™ electrodes and the predicate devices, other than minor configuration differences, is the type of blade coating on some models. The ITI blades are made from a stainless steel alloy with some models having ITI's own stick resistant coating as compared to the predicate devices: 1.) For MegaDyne Medical, stainless steel electrodes with a Teflon™ coating and, 2.) For Aaron Medical, stainless steel electrodes with a "high-tech polymer coating".

Special Controls: Although there are no performance standards established by the FDA for electrosurgical electrode devices, the ITI Medical Technologies, Inc. Electrosurgical Electrodes have been designed to comply with, and are manufactured to pertinent parts of the following standards:

ANSI/AAMI	American National Standard HF18-1993 Electrosurgical devices
ANSI/AAMI	American National Standard 11137 Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization, Third edition.

In addition, the device and its development process also comply with pertinent parts of:

- FDA, CDRH, ODE DGRD: October 19, 1993, 510(k) Guideline General Surgical Electrosurgical Devices and;
- FDA, CDRH, ODE DRAERD: August 16, 1995 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories used in Gastroenterology and Urology.

Data regarding special controls are summarized in the submission, and support the safety and efficacy of the device.

Comparison tests following written protocols were conducted using the ITI devices and the predicate devices. No findings of adverse effects or complications were reported in any of the tests.

The performance evaluations indicate that the ITI Medical Technologies, Inc. Midas Touch™ Electrosurgical Electrodes met all of the performance requirements, consistently performed within their design parameters; and performed equivalently or superior to the predicate devices, thus demonstrating that they are safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Roger W. Werne, Ph.D.
President
ITI Medical Technologies, Inc.
2452 Armstrong Street
Livermore, California 94550

OCT 27 1997

Re: K973234
Trade Name: Midas Touch ™ Electrosurgical Electrodes
Regulatory Class: II
Product Code: GEI
Dated: August 25, 1997
Received: August 28, 1997

Dear Dr. Werne:

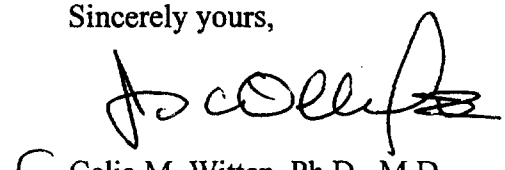
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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 a legally marketed predicate device 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

510(k) Number (if known): 973234

Device Name: **Midas Touch™ Electrosurgical Electrodes**

Statement of intended use:

The ITI Medical Technologies, Inc. Midas Touch™ Electrosurgical Electrodes are intended for use in standard electrosurgical chucks and pencil type accessories wherever standard monopolar electrosurgical cutting and coagulation electrodes are used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973234

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