Rev2

SEP 8 1998

ITI Medical Technologies, Inc.
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Livermore, CA 94550
(925) 371-8305
FAX (925) 371-8222

K982705

SUMMARY OF SAFETY AND EFFECTIVENESS

July 31, 1998

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

Common or Usual Name: Bipolar Forceps

Proprietary Name: Midas Touch™ Bipolar Forceps

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: Ethicon Inc. Non-Stick Bipolar Forceps K973384

Description of Device: The ITI Medical Technologies, Inc. Midas Touch™ Bipolar Forceps family are similar in design to the predicate devices. They have various tip lengths and configurations, and are available in insulated and non-insulated versions. They are made from a stainless steel or Titanium alloy with a proprietary non-stick coating. The proximal end has a protective plastic insulator sheath with industry standard electrosurgery cable connecting pins. Forceps are packaged individually, sold non-sterile, and intended for steam, and EtO sterilization.

Statement of intended use: The ITI Medical Technologies, Inc. Midas Touch™ Bipolar Forceps are intended for use attached by cable to a standard electrosurgical bipolar generator in any general surgery procedure that requires coagulation and or tissue cauterization to achieve hemostasis.

The intended use is identical to that of the predicate devices, i.e. a standard bipolar forceps for use 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™ Bipolar Forceps 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 bipolar electrosurgical generator units and cables as the predicate devices.

The only difference between the Midas Touch™ Bipolar Forceps and the predicate devices, other than minor shape differences, is the type of non-stick coating. The ITI forceps are made from a stainless steel or Titanium alloy having ITI's own non-stick coating as compared to the predicate devices; Kirwan, Nickel forceps and Valleylab, Titanium forceps.

Special Controls: Although there are no performance standards established by the FDA for bipolar forceps devices, the ITI Medical Technologies, Inc. Bipolar Forceps 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

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.
- FDA CDRH ODE March 1995 DRAFT: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance

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.

The performance evaluations indicate that the ITI Medical Technologies, Inc. Midas Touch™ Bipolar forceps 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

SEP 8 1998

Dr. Roger W. Werne
President and CEO
ITI Medical Technologies, Inc.
2452 Armstrong Street
Livermore, California 94550

Re: K982705
Trade Name: Midas Touch Bipolar Forceps
Regulatory Class: II
Product Code: GEI
Dated: July 31, 1998
Received: August 3, 1998

Dear Dr. Werne:

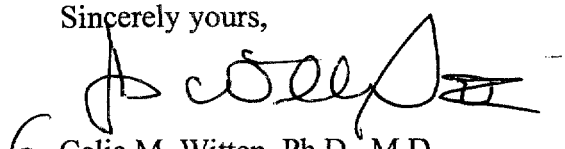
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

510(k) Number (if known): _982705_

Device Name: Midas Touch™ Bipolar Forceps

Statement of intended use:

The ITI Medical Technologies, Inc. Midas Touch™ Bipolar Forceps are intended for use attached by cable to a standard electrosurgical bipolar generator in any general surgery procedure that requires coagulation and or tissue cauterization to achieve hemostasis.

(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 K982705

Prescription Use X
(Per 21 CFR 801.109)

OR

Over - The - Counter - Use_____

(Optional Format 1-2-96)