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510(k) Summary

MAR 25 2011

Traditional 510(k) Notification
Thermedx 37~5™ Electrode Probes
Thermedx, LLC

Applicant
Thermedx, LLC
31200 Solon Rd. Unit#1, Solon Oh 44139
440-542-0883
Contact Person: John R. Scoville, Jr., VP Quality and Regulatory Affairs
Date Prepared: March 23, 2011

Device Name

Proprietary Name:	Thermedx 37~5™ Electrocautery Probes
Common Name:	Electro Cautery Probe
Classification Name:	Electrosurgical Cutting and Coagulation and Accessories (product code GEI)

Indications for Use
The Thermedx 37~5 electrocautery probes are indicated for electrosurgical cutting and coagulation during a variety of urological, gynecological, laparoscopic and general surgical procedures.

Device Description
The Thermedx 37~5 electrode probes are electrosurgical devices which enable the user to have the functions of cutting and coagulation along with suction and irrigation in a single hand held device. These probes are intended to be used in conjunction with the Trumpet valve disposable assembly (model number TV0002). The probes come in a variety of tip configurations. Monopolar electrodes include a J Hook, L Hook, Spatula and Needle tip. . All electrodes have working dimensions of 33 cm in length and 5 mm diameter. Electrodes are manufactured of biocompatible materials per ISO 10993 and are safe, effective and durable for their intended use. All electrodes have an ABS coupling to connect to the trumpet valve disposable assembly and are connected to an electrosurgical unit with a cable of PVC insulation and copper wires.

Substantial Equivalence
The monopolar electrode probes included in the 37~5 fluid management system are substantially equivalent in terms of safety and effectiveness to the following devices.

1. Modulap Disposable Electrosurgical Probes (K994319, KP83623) - ATC Technologies part numbers 4180, 4181, 4182 and 4183
2. Genicon Re-Usable Monopolar Probes (K061417), Genicon, part numbers 707-005-133, 707-005-233 and 707-005-333.
3. Stryker Stiletto Electrosurgical Probe (K963765), Stryker Endoscopy
4. Conmed Electrosurgical Probe (K012018), Conmed

Technological Comparison
This 510(k) Notification demonstrates the substantial equivalence of the Thermedx 37~5 using the substantial equivalence criteria in FDA's K86-3 510(k) Guidance. The new device has the same intended use as the predicate devices, and the minor differences in indications for use statements do not alter the device's intended therapeutic effect. The new device also has similar technological characteristics to those of the predicate devices, and the minor differences are not significant with respect to the safety or effectiveness of the new device. All devices were tested to the same electrical safety and biological testing standards (IEC 601-2-2 and ISO 10993-1) demonstrating equivalence. No animal or clinical test results were required to demonstrate substantial equivalence.

Safety and Effectiveness

The Thermedx 37~5 Electrocautery probes have been developed in accordance with FDA's design controls requirements. The design and development process has ensured that all applicable safety and effectiveness issues are addressed, including but not limited to labeling, sterilization, shelf life, biocompatibility and electrical safety. The product has been fully verified to comply with its established specifications and applicable standards and validated to ensure the device is safe and effective.

All statements and representations set forth above regarding or related to "substantially equivalent" or "substantial equivalence" are in the limited context of the definition and purpose of substantial equivalence in the Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations of the Food and Drug Administration, and are not made in the context of, for any purpose related to, or as an admission against interest under, any other laws or regulations, including patent laws (whether in the context of patent infringement or otherwise).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Thermedx, LLC
% Mr. John R. Scoville
31200 Solon Road, Unit #1
Solon, Ohio 44139

MAR 25 2011

Re: K102275
Trade/Device Name: Thermedx 37-5 Electrocautery Probes, Models: MPJ200, MPL210, MPJ220, MPJ230
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 07, 2011
Received: March 08, 2011

Dear Mr. Scoville:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Form (Text Version)

Indications for Use

510(k) Number (if known):

Device Name: Thermedx 37~5™ Electrocautery Probes

Indications for Use:

The Thermedx 37~5 electrocautery probes are indicated for electrosurgical cutting and coagulation during a variety of urology, gynecology, laparoscopy and general surgery procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102275