K091107

510(k) Summary

Page 1 of 2

MAY - 1 2009

Trade Name:	Model P8400 Hemostatix Thermal Scalpel System
Common Name:	Thermal Scalpel
Classification Name:	Electrosurgical cutting and coagulation device and accessories (§ 878.4400)
Official Contact:	Jeffrey W. Cobb Executive VP Hemostatix Medical Technologies, LLC 8400 Wolf Lake Drive, Ste 109 Bartlett, TN 38133
Telephone:	(901) 261-0012
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Date Prepared:	March 12, 2009

Intended Use – The Model P8400 Hemostatix Thermal Scalpel System is a surgical instrument designed to retain the precise, clean cutting characteristics of a traditional steel scalpel and to minimize blood loss by simultaneously sealing blood vessels as they are cut with minimal tissue damage and virtually no muscle stimulation, using heat thermally conducted to the tissue from an elevated-temperature blade.

Predicate Device – The Model P8400 Hemostatix Thermal Scalpel System is substantially equivalent to the Hemostatix Model 2400Z Thermal Scalpel System and any differences should not affect safety or effectiveness.

Statement of Similarities and Dissimilarities – The Model P8400 Hemostatix Thermal Scalpel System has the same intended use; the same technological characteristics; power modality; mode of operation; utilizes the same scalpel blades; has many of the same audible sounds and alarms; handles that are sterilized the same way (EO gas); same operating temperature ranges (70° C to 300° C), and, utilizes the same blades as the predicate device, the Hemostatix Model 2400Z Thermal Scalpel System cleared via 510(k) No.: K033089. The Model P8400 Hemostatix Thermal Scalpel System differs from the predicate device in that the Model P8400 Hemostatix Thermal Scalpel System features an aluminum enclosure vs. a thermoplastic enclosure for the Hemostatix Model 2400Z Thermal Scalpel System; requires a different handle with a unique plug-in connector which is not compatible with the Hemostatix Model 2400Z Thermal Scalpel System; will accommodate an optional footswitch to control the functions of the handle and blade; will mount on an IV pole unlike the Hemostatix Model 2400Z Thermal Scalpel System; has one multi-color 4.6 in x 3.4 in TFT display vs. two displays (1.5 in x 3 in – three color and 0.5 in x 3 in monochromatic message center); and is designed to be UL 60601-1 Type BF versus a Type B for the Hemostatix Model 2400Z Thermal Scalpel System.

510(k) Summary

Page 2 of 2

Performance Testing – Performance testing of the Model P8400 Hemostatix Thermal Scalpel System was conducted and the results compared to the predicate device – the Model 2400Z Hemostatix Thermal Scalpel System. Results of the following performance tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.

1. **VERIFICATION OF ACTUAL BLADE TEMPERATURES COMPARED WITH CONTROLLER SETPOINTS**

   To verify the design input requirements that the Model P8400 controller was capable of controlling blade temperatures to within ± 10° C of the controller's set points, temperature measurements using a thermocouple attached to a blade surface at controller set points over a range of 150° C and the maximum temperature of 300° C were taken in still air without load applied to the blades using both the Model P8400 controller and the Model 2400Z controller. The results indicated that the actual blade temperature using the Model P8400 controller correlated within 0° C to 5° C over the entire range of the controller's set points. Comparing the results of the Model P8400 controller to that of the Model 2400Z controller, it was concluded that the Model P8400 controller was more capable of matching actual blade temperature to controller set point temperature than the Model 2400Z controller.

2. **VERIFICATION OF THE LEVEL OF HEMOSTASIS ACHIEVED**

   To compare the results of hemostasis achieved with the Model 8400 Hemostatix Thermal Scalpel System to the predicate device, the Model 2400Z Hemostatix Thermal Scalpel System, controlled animal testing was conducted. Results of this testing demonstrated that the P8400 system achieved an average level of hemostasis of 4.8 (as judged on a 0 to 5 scale with 5 representing the best) compared with the Model 2400Z system which achieved an average level of hemostasis of 4.56.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2009

Hemostatix Medical Technologies, LLC
% Underwriters Laboratories, Inc.
Mr. Casey Conry
1285 Walt Whitman Road
Melville, NY 11747

Re: K091107
Trade/Device Name: Model P8400 Hemostatix Thermal Scalpel System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II
Product Code: GEI
Dated: April 15, 2009
Received: April 16, 2009

Dear Mr. Conry:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number:
Device Name: Model P8400 Hemostatix Thermal Scalpel System

Indications For Use:

The Model P8400 Hemostatix Thermal Scalpel System is a surgical instrument designed to retain the precise, clean cutting characteristics of a traditional steel scalpel and to minimize blood loss by simultaneously sealing blood vessels as they are cut with minimal tissue damage and virtually no muscle stimulation, using heat thermally conducted to the tissue from an elevated-temperature blade.

Prescription Use X AND/OR Over-the-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K091107

Page 1 of 1