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510(k) Summary of Safety and Effectiveness

Trade Name:	Hemostatix Model 2400Z Thermal Scalpel System
Common Name:	Thermal Scalpel
Classification Name:	Electrosurgical cutting and coagulation device and accessories (§ 874.4400)

Official Contact:	Gregory Sredin Manager of Regulatory Affairs Gyrus ENT 2925 Appling Road Bartlett, TN 38133
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Date Prepared:	September 19, 2003

The Hemostatix Model 2400Z Thermal Scalpel System is a surgical instrument designed to retain the precise, clean cutting characteristics of the traditional steel scalpel and to minimize blood loss by simultaneously sealing blood vessels as they are cut, with minimum tissue damage and virtually no muscle stimulation, using heat thermally conducted to the tissue from an elevated-temperature blade.

The Hemostatix Model 2400Z Thermal Scalpel System that is described in this notification has the same technological characteristics, power modality and mode of operation as the predicate device. The intended uses are substantially equivalent to the described predicate Oximetrix Shaw Hemostatic Surgical System. The Hemostatix Model 2400Z Thermal Scalpel System is designed to meet *UL 2601-1 including Australian deviations, CSA 22.2 No. 601, IEC 601-1-1 (EN 60601-1), IEC 601-1-2 (EN 60601-1-2), IEC 601-1-4 (EN 60601-1-2), IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 529, ISO 10993-1, EN 55011, Class B.*

The Hemostatix Model 2400Z Thermal Scalpel System is substantially equivalent to the Oximetrix Shaw Hemostatic Surgical System and the difference of the processors that control the units should not affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2004

Mr. Gregory Sredin
Manager of Regulatory Affairs
Gyrus ENT LLC
2925 Appling Road
Bartlett, Tennessee 38133

Re: K033089
Trade/Device Name: Hemostatix Model 2400Z Thermal Scalpel System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 21, 2004
Received: January 22, 2004

Dear Mr. Sredin:

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.

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,

Miriam C. Provost

for 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

Indications for Use

510(k) Number: K033089

Device Name: Hemostatix Model 2400Z Thermal Scalpel System

Indications For Use:

The Hemostatix Model 2400Z Scalpel System is a surgical instrument designed to retain the precise, clean cutting characteristics of the traditional steel scalpel and to minimize blood loss by simultaneously sealing blood vessels as they are cut, with minimum 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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

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

510(k) Number K033089