MAY 2 8 2002

K020778

510(k) Summary of Safety and Effectiveness

Gyrus ENT
Somnoplasty® Model 2420 Tissue Coagulating Electrode

Intended Use/Indications

The Gyrus ENT Somnoplasty® Model 2420 Tissue Coagulating Electrode is intended for use in the coagulation of tissues in the head and neck by qualified medical personnel trained in the use of electrosurgery. Indications for use for the Gyrus ENT Model 2420 Tissue Coagulating Electrode include the coagulation and reduction of enlarged tonsils for patients 13 years of age and older.

Submitted by

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Contact Person

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Date Summary Prepared: March 7, 2002

Name of the Device

Classification Name:	Electrosurgical Cutting and Coagulating Device and Accessories
Common/Usual Name:	Electrosurgical Generator and Tissue Coagulating Electrode
Proprietary Name:	Gyrus ENT Somnoplasty® Model 2420 Tissue Coagulating Electrode

Description and Substantial Equivalence

The Somnoplasty® System is comprised of three principal elements: (1) the Model 2420 Disposable Tissue Coagulating Electrode; (2) the Model RC-20 Reusable Cable*; and (3) the Modified Model S2 Electrosurgical Generator*, or another two-channel Gyrus electrosurgical generator. Previous versions of the Somnoplasty® System have been cleared for use in soft tissue coagulation in the uvula/soft palate (K971450), treatment of nasal obstruction due to chronic turbinate hypertrophy (K973618), and reduction of the incidence of airway obstructions in patients suffering from UARS or OSAS (K982717). *In addition, the current Model S2 Generator was cleared for use in conjunction with disposable soft tissue coagulation electrodes in K001438, and the RC-20 Cable was cleared in K000720.

The Model 2420 Tissue Coagulating Electrode also is substantially the same as the Model 1420 Electrode that was cleared in K000720. Thus, there are no significant differences in design or technological features between the current Somnoplasty® System and the company's previously cleared products. A brief description of each of the components of the current System is provided below.

The Model 2420 Tissue Coagulating Electrode is used to deliver RF energy for selective thermal coagulation of tissue. The electrode is provided as a dual needle that is deployed from a guide sleeve. The angle of deployment is fixed at approximately 45°. The needle is covered proximally by insulation to protect the mucosa during coagulation. A beveled penetrator plate is located at the tip of the guide sleeve and serves to penetrate the tonsil mucosal surface prior to electrode deployment. Temperature sensors located at the tip of the needle and the tip of the insulation monitor lesion temperature.

Like the previously cleared Model 1420 electrode, the Model 2420 provides a slide actuator on the handle used to extend or retract the needle electrodes through attached dual guide lumens. The proximal end of the handle accepts the detachable and reusable power cable. The distal end of the handle is attached to the guide lumens containing the needle electrodes. The entire device is disposable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Jeffrey W. Cobb
Vice President, Regulatory/Clinical Affairs
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Gyrus ENT L.L.C.
2925 Appling Road
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Re: K020778
Trade/Device Name: Gyrus ENT Somnoplasty® Model 2420 Tissue Coagulating Electrode
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 8, 2002
Received: March 11, 2002

Dear Mr. Cobb:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Miriam C. Provost

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 (if known): ~~Not Yet Assigned~~ K020778

Device Name: Gyrus ENT Somnoplasty® Model 2420 Tissue Coagulating Electrode

Intended Use / Indications For Use:

The Gyrus ENT Somnoplasty® Model 2420 Tissue Coagulating Electrode is intended for use in the coagulation of tissues in the head and neck by qualified medical personnel trained in the use of electrosurgery. Indications for use for the Gyrus ENT Model 2420 Tissue Coagulating Electrode include the coagulation and reduction of enlarged tonsils for patients 13 years of age and older.

Contraindications for Use: The use of the Somnoplasty® System is contraindicated when, in the judgment of the physician, electrosurgical procedures would be contrary to the best interests of the patient.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR **Over-The-Counter Use** ____ (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020778