K021777

AUG 26 2002

510(k) Summary of Safety and Effectiveness

G II Radio-frequency Workstation & Accessories

Submitted by:

Gyrus ENT
2925 Appling Rd.
Bartlett, TN 38133

Contact Person:

Jeffrey W. Cobb

Vice President, Regulatory/Clinical Affairs & Quality

Telephone: 901-373-2673
Facsimile: 901-373-0242

Date Summary Prepared: August 19, 2002

Name of the Device: G II Radio-frequency Workstations

Common/Usual Name: Electrosurgical Generator and Accessories

Classification Name: Electrosurgical Cutting & Coagulation Device and Accessories (per 21 CFR 878.4400)

Predicate Devices:

- Gyrus ENT Somnoplasty Generator (K020067)
- Gyrus Medical Inc PlasmaKinetic Generator (K003060)
- Arthrocare Sinus Electrosurgery Generator (K973478)
- Arthrocare ENTec Plasma Wands (K014290)
- ENTec EVac Plasma Wands (K011279)
- Gyrus ENT (Smith & Nephew) Hemostatix Scalpel (K002021)
- Gyrus ENT TCRF Somnoplasty Electrodes (K982717), (K973618), (K971450), & (K020778)

Description:

The Gyrus ENT G II RF Workstation is a combination of two previously cleared radio-frequency generators:

1. The Gyrus ENT Somnoplasty Temperature-Controlled Radio-frequency Generator – K020067, and
2. The Gyrus Medical Inc. (formerly Everest Medical Corporation) PlasmaKinetic™ Generator – K003060.

Somnoplasty TCRF Generator Section of the GII RF Workstation

Statement of Intended Use: The Gyrus ENT Somnoplasty Generator section of the G II Radio-frequency Workstation is indicated for coagulation of soft tissue including:

	Indication	Predicate Device 510(k)
1.	The coagulation of enlarged tonsils in patients 13 years of age and older	K020778
2.	The reduction of the incidence of airway obstructions, e.g., base of tongue, soft palate, etc., in patients suffering from UARS or OSAS	K982717 K971450
3.	Tissue coagulation in the inferior turbinates	K973618
4.	Tissue coagulation in the uvula/soft palate which may reduce the severity of snoring in some individuals	K982717 K971450

PlasmaKinetic Generator Section of the GII RF Workstation

The PlasmaKinetic Generator section of the GII RF Workstation uses those bipolar and PlasmaCision instruments described in our original submission (K021777) dated May 29, 2002, and subsequent correspondence related to K021777 dated July 10, 2002, and July 19, 2002.

As stated in the original submission, K021777, the PlasmaKinetic Generator section of the GII RF Workstation is substantially equivalent to the ArthroCare ENTec Plasma Wand cleared under 510(k) Nos. K014290, K013463, K011279, K000228, and K973478. **Testing was presented in our July 19, 2002, supplement to K021777 that demonstrated the The PlasmaKinetic Generator section of the GII RF Workstation performed similarly to the ArthroCare ENTec Plasma Wand.**

Statement of Intended Use: The PlasmaKinetic Generator section of the GII RF Workstation is indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (ENT) surgery including:

	Indication	Predicate Device 510(k)
1.	Adenoidectomy	K014290
2.	Cysts	K014290
3.	Head, Neck, Oral, and Sinus Surgery	K014290
4.	Mastoidectomy	K014290
5.	Myringotomy with effective Hemorrhage Control	K014290
6.	Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates	K014290
7.	Nasopharyngeal / Laryngeal indications including Tracheal Procedures, Laryngeal Polypectomy, and Laryngeal Lesion Debulking	K014290
8.	Neck Mass	K014290
9.	Papilloma Keloids	K014290
10.	Submucosal Palatal Shrinkage	K014290
11.	Tonsillectomy	K014290
12.	Traditional Uvulopalatoplasty (RAUP)	K014290
13.	Tumors	K014290
14.	Tissue in the Uvula/Soft Palate for the Treatment of Snoring	K014290

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

The Gyrus ENT **G II Radio-frequency Workstation** has two modes of operation:

- The monopolar mode has controls for maximum temperature and energy delivered. The unit has readouts for total energy delivered, impedance, temperature for two thermocouples and time of energy delivery.
- The bipolar mode has controls for output waveform type and power. The unit has readouts for set power and waveform.

Connectors on the front panel include the monopolar connector for active electrode and dispersive electrode and separate dual bipolar connectors for PlasmaCision electrodes and bipolar instruments. The foot pedal is connected on the back panel. Accessories included with the **G II Radio-frequency Workstation** include the PlasmaCision electrodes, bipolar instruments, connector cable, footswitch and a power cable.

Comparison to Predicate Devices:

The Gyrus ENT **G II Radio-frequency Workstation** has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance testing has been done to validate the performance of the device. The comparison and validation results presented show that the device is substantially equivalent to predicate devices and is safe and effective in its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2002

Gyrus ENT
Jeffrey W. Cobb
Vice-President, Regulatory/Clinical Affairs & Quality
2925 Appling Road
Bartlett, Tennessee 38133

Re: K021777
Trade/Device Name: Gyrus G II Radio-frequency Workstation & Accessories
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting & coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 29, 2002
Received: May 30, 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.

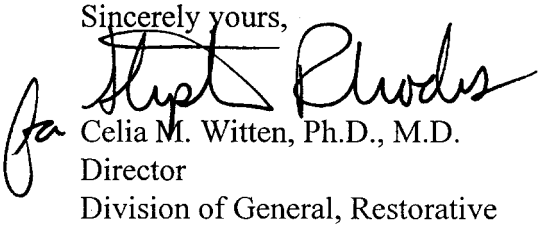
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21 CFR 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,



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

Exhibit A

Indications for Use

510(k) Number (if known): K021777

Device Name: G II Radio-frequency Workstation & Accessories

Indications For Use:

The PlasmaKinetic Generator section of the GII RF Workstation is indicated for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (Head and Neck) surgery including:

- Adenoidectomy
- Cysts
- Head, Neck, Oral, and Sinus Surgery
- Mastoidectomy
- Myringotomy with effective Hemorrhage Control
- Nasal Airway Obstruction by Reduction of Hypertrophic Nasal Turbinates
- Nasopharyngeal / Laryngeal indications including Tracheal Procedures, Laryngeal Polypectomy, and Laryngeal Lesion Debulking
- Neck Mass
- Papilloma Keloids
- Submucosal Palatal Shrinkage
- Tonsillectomy
- Traditional Uvulopalatoplasty (RAUP)
- Tumors
- Tissue in the Uvula/Soft Palate for the Treatment of Snoring

The Gyrus ENT Somnoplasty TCRF Generator section of the GII RF Workstation with the Temperature Controlled Radio-frequency (Somnoplasty®) Electrodes is indicated for coagulation of soft tissue including:

> The coagulation of enlarged tonsils in patients 13 years of age and older; the reduction of the incidence of airway obstructions, e.g., base of tongue, soft palate, etc., in patients suffering from UARS or OSAS; tissue coagulation in the inferior turbinates; and tissue coagulation in the uvula/soft palate which may reduce the severity of snoring in some individuals.

The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment and familiar with potential complications that may arise during or following Head and Neck surgery.

Contraindications for Use:

There are no known absolute contraindications to the use of radio-frequency surgery. The use of the Gyrus ENT G II Radio-frequency Workstation is contraindicated when, in the judgement of the physician, electrosurgical procedures would be contrary to the best interests of the patient. The use of the system is also contraindicated for patients with heart pacemakers or other electronic device implants.

(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)

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

510(k) Number K021777