K041285

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510(k) Summary of Safety and Effectiveness

Gyrus G3 System (Generator & Accessories)

Submitted by:

Gyrus Medical Ltd
Fortran Road
St Mellons,
Cardiff CF30LT
UK

Contact Person:

Andrew Dzimitrowicz
Quality Manager

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Date Summary Prepared: 11th May 2004

Name of the Device:

Proprietary Name:	Gyrus G3 System (Generator & Accessories)
Project Name:	G3
Common/Usual Name:	Electrosurgical Generator and Accessories
Classification Name:	Electrosurgical Cutting & Coagulation Device and Accessories (per 21 CFR 878.4400)
Brand Name:	Not yet assigned
Predicate Devices:	K021777 (G2 Radio-frequency Workstation & Accessories)

Description:

The Gyrus G3 System Generator has two principal 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 generator are the electrodes, connector cable, footswitch and a power cable.

Statement of Intended Use:

The Gyrus G3 System is intended for use for ablation, resection and coagulation of soft tissue and hemostasis of blood vessels in otorhinolaryngology (Head and Neck) surgery coagulation of soft tissue.

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

Comparison to Predicate Devices:

The Gyrus G3 System 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 in this 510(k) notification to the FDA 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

SEP 1 0 2004

Mr. Andrew Dzimitrowicz
Director of RA/QA
Gyrus Medical Ltd.
Fortran Road, St. Mellons
Cardiff
United Kingdom CF3 OLT

Re: K041285
Trade/Device Name: Gyrus G3 Radio-Frequency Workstation and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 13, 2004
Received: July 16, 2004

Dear Mr. Dzimitrowicz:

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,

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~~ K041285

Device Name: Gyrus G3 Radio-frequency workstation & Accessories

Indications For Use:

The Bipolar Generator section of the G3 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
- Uvulopalatopharyngoplasty (UPPP)
- Parotidectomy
- Radical Neck Disection

The Gyrus Somnoplasty TCRF Generator section of the G3 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 G3 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 active device implants.

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

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

Miriam C. Provost

~~Concurrence of CDRH, Office of Device Evaluation (ODE)~~

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

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