JUL 2 1 2003

K031085

510(k) Summary of Safety and Effectiveness

Gyrus PlasmaKinetic Superpulse System (Generator & Accessories)

Submitted by:

Gyrus Inc
6655 Wedgwood Road Suite 105
Maple Grove
Minnesota 55311

Contact Person:

Mercedes Bayani
Director Regulatory Affairs and Clinical

Telephone: (763) 416-3015
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Date Summary Prepared: 2003

Name of the Device:

Proprietary Name: Gyrus PlasmaKinetic Superpulse System (Generator & Accessories)

Project Name: Superpulse

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:

Gyrus Inc PlasmaKinetic Generator (K003060)
Gyrus Medical Ltd PlasmaKinetic Endourology Generator (K003569)
Gyrus Medical Ltd Endourology Axipolar Resectoscope Electrode (K001270)

Description:

The Gyrus PlasmaKinetic Superpulse System Generator is an Electrosurgical device with a bipolar mode of operation:

The generator has controls for output waveform type and power. The unit has readouts for set power and waveform.

The two physically identical connectors on the front panel support PlasmaKinetic, PlasmaKinetic Superpulse (RHS only) and 4mm 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 PlasmaKinetic Superpulse System is intended for use for ablation, removal, resection and coagulation of soft tissue and where associated hemostasis is required

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

Comparison to Predicate Devices:

The Gyrus PlasmaKinetic Superpulse 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

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Ms. Mercedes Bayani
Director, Regulatory Affairs and Clinical
Gyrus, Inc.
6655 Wedgwood Road, Suite 105
Maple Grove, Minnesota 55311

Re: K031085
Trade/Device Name: Gyrus PlasmaKinetic Superpulse System (Generator & Accessories)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 3, 2003
Received: April 24, 2003

Dear Ms. Bayani:

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. 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) you may obtain. 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,

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 (if known): K031085

Device Name: Gyrus PlasmaKinetic Superpulse System Generator & Accessories
ELECTROSURGICAL GENERATOR

Indications For Use:

The Gyrus PlasmaKinetic Superpulse System is intended for use for ablation, removal, resection and coagulation of soft tissue and where associated hemostasis is required in open, endoscopic and laparoscopic surgical procedures.

The device is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

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

510(k) Number K031085

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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