OCT 2 2 2004

K041633

510(k) Summary of Safety and Effectiveness

Gyrus PlasmaCision Laparoscopic Spatula

Submitted by: Gyrus Medical Inc.
6655 Wedgwood Road
Maple Grove, MN 55311-3602

Contact Person: David E. Chadwick, Ph.D., RAC
Director, Regulatory Affairs/Quality Assurance/Clinical

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Date Summary Prepared: June 15, 2004

Name of the Device:

Proprietary Name:	Gyrus PlasmaCision Laparoscopic Spatula
Project Name:	Laparoscopic Spatula
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 PK Bipolar Needle Electrode K031079 Gyrus PK Bipolar L Hook Electrode K031082 Gyrus PlasmaCision Scimitar Instrument K021777

Description:

The Gyrus PlasmaCision Laparoscopic Spatula is a bipolar electrosurgical instrument with the capability to cut and coagulate soft tissue and blood vessels in laparoscopic surgery under carbon dioxide gas or air insufflation. The instrument will pass through a 5mm cannula or through an operating laparoscope's working channel of 5mm minimum diameter.

The instrument is to be used only with the Gyrus PlasmaKinetic Generator, the Gyrus SuperPulse Generator and associated 5 way connector cable.
The device is intended for use in a non-irrigated (dry) environment.

The device has the functionality to dissect, resect or vaporise tissue with haemostasis, to coagulate tissue and blood vessels and to blunt (cold) dissect tissue.

Statement of Intended Use:

The Gyrus PlasmaCision Laparoscopic Spatula is indicated for resection and coagulation of soft tissue and blood vessels in laparoscopic surgery when used with the Gyrus PlasmaKinetic Generator or the Gyrus SuperPulse Generator. This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Comparison to Predicate Devices:
The Gyrus PlasmaCision Laparoscopic Spatula 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

OCT 2 2 2004

David E. Chadwick, Ph.D., RAC
Director, Regulatory Affairs/Quality Assurance/
Clinical
Gyrus Medical, Inc.
6655 Wedgwood Road
Maple Grove, Minnesota 55311

Re: K041633
Trade/Device Name: Gyrus PlasmaCision Laparoscopic Spatula
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 6, 2004
Received: October 7, 2004

Dear Dr. Chadwick:

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 (240) 276-0115. 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 (if known): K041633

Device Name: Gyrus PlasmaCision Laparoscopic Spatula

Indications For Use:

The Gyrus PlasmaCision Laparoscopic Spatula is indicated for resection and coagulation of soft tissue and blood vessels in laparoscopic and general surgical procedures when used with the Gyrus PlasmaKinetic Generator or the Gyrus PlasmaKinetic SuperPulse Generator.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use __
(Per 21 CFR 801.109)

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

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

510(k) Number K041633