OCT 2 4 2005

K050460

510(k) Summary of Safety and Effectiveness
Gyrus L09 Instrument

Submitted by: Gyrus Medical, Inc.
6655 Wedgwood Road, Suite 160.
Maple Grove, MN 55311-3602

Contact Person: Mark A. Jensen
Group Vice President Regulatory Affairs/Quality Assurance

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Date Summary Prepared: October 18, 2005

Name of the Device:

Proprietary Name:	Gyrus PlasmaCision and PlasmaBlend electrodes
Project Name:	L09 Instrument
Common/Usual Name:	Electrosurgical Accessory
Classification Name:	Electrosurgical Cutting & Coagulation Device and Accessories (per 21 CFR 878.4400)
Brand Name:	Not yet assigned

Predicate Devices: K031082 - PK Bipolar L Hook
K041285 - Gyrus G3 System (Generator and Accessories)

Description

General:

The Gyrus PlasmaCision and PlasmaBlend electrodes are bipolar electrosurgical instruments 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 working channel of 5mm or larger diameter. The PlasmaCision and PlasmaBlend electrodes may also be used in general surgical procedures.

The instruments are to be used only with the Gyrus General Surgery RF Workstation. Activation of the instruments is achieved via footswitch control.

Variants available:

The Instruments are available with and without aspiration (suction) / irrigation lines. On such equipped instruments, this provides additional functionality to the device by increasing its range of capabilities within the procedure. The suction / irrigation capable versions incorporate a lumen / Y connector and male connector with polymeric tubing for adaptation to suction / irrigation systems.

The instruments are, like other Gyrus bipolar electrosurgical instruments, available in a number of different shaft lengths and diameters, chosen by the surgeon to be most appropriate for the procedure to be undertaken.

Indication:

The instruments are indicated for Bipolar electrosurgical resection and coagulation of soft tissue and blood vessels in laparoscopic or general surgical procedures.

Construction:

The instruments have a multipole arrangement at the patient interface. The instruments consist of three individually isolated conductors that act as the tissue effectors.

E07 Generator Output to the L09 Instrument:

A PlasmaBlend output is a blended cut and coagulation output that is delivered to the L09 instrument. The ratio of cut to coagulation of this output is selectable by the user and this allows the user to select the amount of haemostasis created during cutting. This output is controlled by the Gyrus General Surgery RF Workstation.

Classification:

The instruments are Class II medical devices.

The system and therefore these instruments are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Comparison to Predicate Devices:

The instruments are a development of a previously cleared electrosurgical instrument, the PK Bipolar L Hook, cleared in 510(k) No. K031082. The instruments has the same intended use of Electrosurgical coagulation, cutting and dissection with aspiration (suction) and irrigation. Its functionality is the same as the previously cleared Gyrus ENT PlasmaCision Electrode, the OPI, cleared in 510(k) No. K041285 with suction (aspiration).

The instruments has been carefully compared to the 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 4 2005

Mark A. Jensen
Group Vice President Regulatory
Affairs/Quality Assurance
Gyrus Medical, Incorporate
6655 Wedgwood Road, Suite 160
Maple Grove, Minnesota 55311-3602

Re: K050460
Trade/Device Name: Plasmacision and Plasmablend Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 22, 2005
Received: September 23, 2005

Dear Mr. Jensen:

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/industry/support/index.html

Sincerely yours,

Barbara Bruckner
for

Mark N. Melkerson
Acting 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): K050460

Device Name: Plasmacision and Plasmablend Electrodes

Indications For Use: The Plasmacision and Plasmablend Electrodes are indicated for Bipolar electrosurgical resection and coagulation of soft tissue and blood vessels in laparoscopic or general surgical procedures.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenner - for MKM

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

510(k) Number K050460