Olympus Surgical Technologies of America
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough, MA 01772

510(K) SUMMARY

DEC 0 5 2012

General Information

Manufacturer:	Gyrus Medical, Ltd. Fortran Road, St. Mellons Cardiff CF3 OLT ERN: 9617070
510(k) Submitter:	Gyrus ACMI Inc. 136 Turnpike Rd. Southborough, MA 01772-2104 ERN: 3003790304
Contact Person:	Neil Kelly (508) 804-2690 neil.kelly@Olympus-OSTA.com
Date Prepared:	August 24, 2012
Classification Name:	Coagulator-Cutter, Endoscopic, Bipolar (And Accessories) Obstetrics/Gynecology HIN 21 CFR 884.4150 Class II
Trade Name:	PKS™ BiLL™
Generic/Common Name:	BiLap Loop / Bipolar Laparoscopic Loop

Predicate Device

Gyrus ACMI PKS™ BiLL™	K111059

Indications for Use

The PKS™ (Plasmakinetic System) BiLL™ (Bipolar Laparoscopic Loop) instrument is a 5mm bipolar electrosurgical device. The device is intended to be used for the amputation of the mobilised uterus during Laparoscopic Supracervical (Subtotal) Hysterectomy and the resection of devascularized subserosal pedunculated myomas. It is used in conjunction with the Gyrus ACMI G400 Workstation Generator.

Product Description

The Bipolar Laparoscopic Loop is a single use disposable high frequency RF bipolar accessory to be used in conjunction with the G400 generator. It is available in an 88mm x 227mm loop size. The device is sterile for single use sterilized by gamma irradiation to an SAL of 10^{-6}.

Performance Data Technological features and Substantial Equivalence

The PKS™ BiLL™ utilizes features incorporated into the following legally marketed predicate device:

- The bipolar PKS™ BiLL™ connects to the same electrosurgical generator, G400 (K050550) as the predicate PKS™ BiLL™ (K111059).
- The PKS™ BiLL™ uses Bipolar PK (Plasma Kinetic) technology and contains an identification capacitor embedded in the single use connector cable will be recognized by the generator to set default optimal power output parameters for the subject instrument. This remained unchanged and identical to the predicate PKS™ BiLL™ (K111059).
- The mechanical design features of the PKS™ BiLL™ are similar to that of the predicate PKS™ BiLL™ (K111059).

The proposed PKS™ BiLL™ has the identical Indications for use as the predicate PKS™ BiLL™.

The PKS™ BiLL™ instrument is compliant to electrical standards specifically to those applicable sections of IEC 60601 incorporating electrical, thermal safety and Electromagnetic Interference.

The PKS™ BiLL™ instrument uses materials that are well established and used in other GYRUS ACMI FDA cleared medical devices. Biocompatibility testing on all patient contacting parts has been performed in compliance to the relevant requirements of ISO-10993.

The PKS™ BiLL™ instrument is packaged and sterilized as a sterile single use device.

Bench, Biocompatibility, and General Safety Summary

Design verification testing was carried out to ensure the device meets the product specifications, and design validation was carried out to ensure the product meets the user requirements. All testing was completed successfully. Electrical testing was also carried out to IEC 60601 and passed as well.

In addition the representative final product was tested to and passed ISO-10993-1. The product has been determined to be biocompatible.

Pre-clinical Evaluation Summary

In addition a pre-clinical evaluation was carried out using extirpated tissue (Human Uterine), and three (3) Physicians. Thirty-two (32) questions were asked of each of the three physicians after they carried out a mock procedure using the proposed device. These questions ranged from ease of understanding the IFU, to performance related questions specific to the

procedure. All three physicians were happy with the proposed device and felt it met their needs and performed to their expectations.

Summary

The proposed Gyrus ACMI Inc. Bipolar Laparoscopic Loop (PKS™ BiLL™), as described in this submission, is substantially equivalent to the predicate in intended use, materials, principles of operation and fundamental scientific technology and raises no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 5, 2012

Gyrus ACMI, Inc.
% Mr. Neil Kelly
Regulatory Affairs Specialist
136 Turnpike Road
SOUTHBOROUGH MA 01772

Re: K122605
Trade/Device Name: Gyrus ACMI® Bipolar Laparoscopic Loop (PKS™ BILL™)
Regulation Number: 21 CFR§ 884.4150
Regulation Name: Bipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: HIN
Dated: November 2, 2012
Received: November 5, 2012

Dear Mr. Kelly:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert R. Lerner

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K122605

Device Name: Gyrus ACMI® Bipolar Laparoscopic Loop (PKS™ BiLL™)

Indications for Use:

The PKS™ (Plasmakinetic System) BiLL™ (Bipolar Laparoscopic Loop) instrument is a 5mm bipolar electrosurgical device. The device is intended to be used for the amputation of the mobilised uterus during Laparoscopic Supracervical (Subtotal) Hysterectomy and the resection of devascularized subserosal pedunculated myomas. It is used in conjunction with the Gyrus ACMI G400 Workstation Generator.

Prescription Use: __ X __ OR Over-the-Counter Use: _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122605