K100816

510(k) Summary of Safety and Effectiveness

Gyrus ACMI, Inc.
Gyrus ACMI PK® SuperPulse® System

General Information

Manufacturer:	Gyrus Medical Ltd Fortran Road, St Mellons Cardiff, CF3 0LT, UK
Establishment Registration Number:	9617070
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Graham A. L. Baillie Senior Regulatory Specialist
Date Prepared:	March 19, 2010

Device Description

Classification:	Endoscopic Electrosurgical Unit and Accessories Class 2, 21 CFR 876.4300 Gastroenterology-Urology Panel, and Electrosurgical Cutting and Coagulation Device and Accessories Class 2, 21 CFR 878.4400 General and Plastic Surgery Panel
Product Code(s):	GEI and KNS
Project Name:	PK® SuperPulse® System Generator® with TURis Electrodes
Trade Name(s):	Gyrus ACMI PK® Superpulse® System (Generator, accessories)
Generic/Common Name:	Electrosurgical Generator and Accessories

Predicate Devices

Gyrus PlasmaKinetic™ SuperPulse® System	K031085
Olympus XUES-41 Electrosurgical Unit and accessories	K030194
Gyrus ACMI PK® SuperPulse® System	K082054

Intended Use

The Gyrus ACMI PK® Superpulse® System Generator is intended for use with Gyrus ACMI PK® Bipolar Instruments, Olympus TURis Bipolar Electrodes, PK® Endourology Electrodes with PK® resectoscope or urological endoscope with 5 Fr or larger working channels and PK® Electrodes used in open, laparoscopic, and endo-urology procedures for cutting, coagulation, removal or ablation of soft tissue and where associated hemostasis is required in urological electrosurgical procedures.

Product Description

The proposed PK® SuperPulse® System Generator and its software will be modified to allow the use of the Olympus TURis resectoscope and associated instruments. This functionality would be in addition to the existing released support for the Gyrus ACMI resectoscopes and compatible electrodes.

Modifications include:

- Modification to the Superpulse® software to add an additional instrument band to allow the connection of a TURis specific connector cable.Addition of a saline monitoring facility to ensure that energisation is only applied to the TURis connector cable when a saline environment is sensed.Modification to User Manual to cover the above changes

The target applications and intended use for the PK® Superpulse® System Generator with the new software are unchanged from the previously marketed PK® Superpulse® System.

Technological Characteristics and Substantial Equivalence

A new ID band has been assigned for a new instrument connection cable that will support the range of Olympus TURis instruments (The name TURis is derived from transurethral resection in saline).

Default settings and adjustments will be available to all Olympus TURis instruments connected to this TURis cable. The default settings and range of adjustment for these instruments have been provided by OWI (Olympus Winter und Ibe) located in Hamburg, Germany.

A new saline detection feature will be incorporated in the SuperPulse® software to ensure that saline is present before activation will be allowed to occur with Olympus TURis electrodes.

Continued...Technological Characteristics and Substantial Equivalence

The technical risk for the software release is low. This is because the project is replicating a feature already available on the Olympus UES-40 generator; information about the implementation of this feature is readily available. The performance of the saline detection feature should be such that it operates in a similar manner to that of the existing Olympus UES-40 generator used for TURis accessories. The power level used to sense the impedance is to be kept similar to the same low level as the UES-40 as this has been clinically accepted in the marketplace.

The purpose of the saline detection feature is to prevent activation in non-approved irrigants other than saline (e.g. glycine) that are typically used in monopolar based urology procedures. The saline detection facility will result in a warning message if the impedance of the tissue / saline is sensed above a fixed threshold.
The new feature will be specific to the Olympus TURis band and existing alternative non-TURis product performance will be unchanged.

The proposed Gyrus ACMI PK® SuperPulse® System will have the same indications for use as the existing/predicate and its intended use will differ only in that it will be intended to support the additional Olympus TURis cable and electrodes. In summary, the PK® SuperPulse® System Generator is substantially equivalent to the predicate device and presents no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Gyrus Acmi, Inc.
% Mr. Graham A.L. Baillie
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K100816
Trade/Device Name: Gyrus ACMI PK® SuperPulse® System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, KNS
Dated: June 24, 2010
Received: June 25, 2010

Dear Mr. Baillie:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Gyrus ACMI PK® SuperPulse® System

Indications for Use:

The Gyrus ACMI PK® 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.

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100816