510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
PK® Button Electrode

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:	Neil Kelly Regulatory Affairs Specialist 508.804.2690 neil.kelly@olympus-OSTA.com
Date Prepared:	June 4, 2012

Device Description

Classification Name:	Electrode, Electrosurgical, Active, Urological Class 2 21 CFR 876.4300 Gastroenterology/Urology Panel
Project Name:	Gyrus ACMI PK® Button Electrode
Trade Name(s):	Bipolar Vaporization and Coagulation Electrode
Generic/Common Name:	Electrosurgical vaporization and coagulation device

Predicate Devices

Gyrus ACMI PK Button Electrode (K093181) – Existing design
Olympus HF-Resection Electrodes (K102781) – Existing design / desired indications
Gyrus ACMI SuperPulse System (K100816) – Common generator

Intended Use

The Gyrus ACMI PK® Button Electrode is a bipolar instrument intended for use in urological electrosurgical procedures involving the ablation or removal of soft tissue and where associated hemostasis is required. The specific urological indication for the PK® Button device is Transurethral Vaporization of the prostate (TUVP/TVP) for benign prostatic hypertrophy, and for Transurethral Vaporization of bladder tumors. The PK® Button is not to be used to resect tissue.

Product Description

The PK® (PlasmaKinetic) electrodes works by exploiting the electrically conductive properties of saline irrigating fluid and wet tissue at the operative site to form a conductive field. Energy is delivered from the Generator, through the proposed electrode, and to the operative site when the footswitch is activated. The proposed electrode is used through a resectoscope to reach the operative site. Irrigating fluid (saline) exits the resectoscope via the attached continous flow sheath and wets the tissue at the operative site prior to the use of the proposed electrode. RF energy is conducted through the irrigating field to the tissue to vaporize and/or coagulate the tissue.

The PK® Button Electrode has a button shaped distal tip with connecting arms, with an electrode shaft, and connector cable at the proximal end. The single use Gyrus ACMI PK® Button Electrode will be provided sterile and packaged with a single use electrical connector cable. The distal end of the connector cable is secured to the working element of the Gyrus ACMI Elite Resectoscope (K021166). A three pin plug on the proximal end of the cable connector is secured to the generator. An ID capacitor molded into the connector cable allows the generator to use its instrument recognition feature to automatically configure the system for optimal safe performance with the Gyrus ACMI PK® Button Electrode. This is the identical technology used in the predicate devices, including (K093181 and K102781).

Like the predicate K093181, and K102781 the distal tip of the electrode is a Stainless Steel 304 button measuring 3.16mm in diameter. Two Pt-Ir 70%-30% wires are welded, formed and drawn into the return arms to connect to the active wire. At the distal tip, the Pt-Ir 70%-30% arms are insulated with PVDF heat shrink and then clad with PTFE sleeve. The PVDF insulated Pt-Ir 70%-30% wires are threaded through the ceramic tubes and then through the return loop arm assembly. The gap between the ceramic-return tube and ceramic-PVDF insulation are sealed with Epo-Tek (an epoxy-resin) to form a

watertight seal. The distal tip and the return tubes assembly are known to have direct contact with patient during use.

The proposed device is identical to the existing PK Button K093181, and of the same fundamental scientific technology as the predicate HF Resection/Vaporization electrode K102781. The distal tip of the electrodes are identical (304 SS), the connector arms are identical (Pt-Ir 70%-30%), and the Electrode sleeve is also identical (PTFE). The predicate K10281 device has no additional design features/functions that make it safer and/or more effective than the proposed device for transurethral vaporization of bladder tumors. The devices are of the same design, and same fundamental scientific technology. There are no new risks created or identified by expanding the indications for use on the proposed device to match that of the predicate devices.

Technological Characteristics and Substantial Equivalence

The proposed PK® Button utilizes features incorporated into the following legally marketed predicate devices:

- The proposed PK® Button Electrode connects to the same electrosurgical generator as the predicate PK® Button Electrode, and predicate Olympus HF Resection/Vaporization Electrode.
- An identification capacitor is imbedded in the single use connector cable and will be recognized by the generator to set default optimal power output parameters for the subject instrument
- The PK® Button uses the same patient-contacting materials that are utilized in the predicate devices.

The PK® Button will have the same intended use and similar indications as the predicate PK Button Electrode (K093181) with the addition of " and Transurethral Vaporization of bladder tumors". The predicate Olympus HF Resection Electrodes (K102781) already has this additional indication, and has the same intended use, design, and scientific technology as the proposed device.

The bipolar vaporization and coagulation performance of the PK® Button is identical to the known tissue vaporization and coagulation performance characteristics of the predicate PK® Button electrode, as it is the exact same device. Althouugh the predicate PK Button lacks the transurethral vaporization of bladder tumors indication it was selected to demonstrate the device is currently on the market, and cleared for use by the FDA via K093181. The proposed device is also of the same design and scientific technology as the predicate Olympus HF-Resection Electrodes (K102781), which carries a transurethral vaporization of bladder tumors, the proposed devices desired indication. In addition, the PK® SuperPulse® Generator is the same generator that provides bipolar energy to the currently marketed predicate PK® Button Electrode (K093181) and the currently marketed Olympus HF-Resection Electrodes (K102781). Bench and animal

testing in predicate submissions demonstrated that the performance requirements were met. In addition the current risk analysis was reviewed and there were no new risks identified by expanding the indication that were not already covered in the original risk analysis.

In summary, the PK® Button electrode is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy. Please see Sections 8, 9, and 10 for a more details.

In addition, the following standards are applicable:
IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic Compatibility – Requirements and Tests

IEC 60601-2-2 - Medical electrical equipment - Part 2-2: Particular Requirements for the safety of High Frequency Surgical Equipment.

IEC 60601-2-18 – Medical electrical equipment – Part 2-18 Particular requirements for the basic safety and essential performance of endoscopic equipment.

AAMI/ANSI/ISO 11135-1: Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization

AAMI/ANSI/ISO 11607-1- Packaging for Terminally Sterilized Medical Devices

AAMI/ANSI/ISO 10993-1 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUN 2 0 2012

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

Re: K120567
Trade/Device Name: Gyrus ACMI PK® Button Electrode
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FAS, GEI
Dated: June 4, 2012
Received: June 8, 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,

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

K120567

Indications for Use

510(k) Number: K120567

Device Name: Gyrus ACMI PK® Button Electrode

Indications for Use:

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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 Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120567