DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 19, 2014

Gyrus ACMI Incorporated
Mr. Neil Kelly, MBA, RAC
Senior Regulatory Affairs Specialist
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K142154
Trade/Device Name: PK Needle
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 25, 2014
Received: November 26, 2014

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142154

Device Name
PK Needle

Indications for Use *(Describe)*
The PK Needle is indicated for resection of soft tissue in laparoscopic and general surgical procedures when used with the Olympus ESG-400 Generator.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.

Olympus PK Needle

General Information

Manufacturer:	Gyrus ACMI, Inc. 6655 Wedgwood Road Maple Grove, MN 55311 Phone: 508-804-2739
Establishment Registration Number:	2183680
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Neil Kelly Senior Regulatory Affairs Specialist 508-804-2690 Neil.kelly@olympus-osta.com
Date Prepared:	August 1, 2014

Device Description

Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulation number	21 CFR 878.4400
Product code	GEI
Regulatory class	Class II
Review Panel	General and Plastic Surgery
Trade Name:	Olympus - PK Needle
Generic/Common Name:	Electrosurgical cutting and coagulation device

Predicate Devices

Everest Bipolar Needle Electrode Gyrus Bipolar Needle	K031079

Comparison to Predicate Devices:

The Olympus - PK Needle has been compared to our own legally marketed Everest Bipolar Needle Electrode (K031079) with respect to intended use and technological characteristics. The comparison and testing results presented in this 510(k) notification show that the device is substantially equivalent to predicate devices and raises no new concerns or safety or effectiveness.

Product Description

The PK Needle is a bipolar electrosurgical instrument with the capability to resect soft tissue and blood vessels in laparoscopic and general surgical procedures. The instrument will pass through a 5mm cannula or through an operating laparoscope working channel of 5mm or larger diameter. The device has an active blunt needle shaped tip and is activated via a button on the handle, or by a foot pedal. The proposed device plugs into the Olympus ESG-400 generator (K141225). The generator and device make up a medical electrical system. The instrument is to be used only with the Gyrus ESG-400 Generator.

Technological Characteristics

For safety and convenience the Olympus ESG-400 generator recognizes and automatically presets the default output settings once the proposed PK Needle is connected.

The PK Needle is activated using a button located on the device handle, or via a foot pedal.

Material

The predicate and proposed devices share many common materials. The two patient contact material differences are the sheath, which is now flouropolymer rather than Polyimide tubing, and a new ink was added on the device shaft as well. Biocompatibility testing has been carried out with passing results. As for the electrode tip and insulation all materials remain the same as the predicate.

Intended Uses

The PK Needle is indicated for resection of soft tissue in laparoscopic and general surgical procedures when used with the Olympus ESG-400 Generator.

Compliance to Voluntary Standards

The design of the proposed device complies with the following standards:

ISO 10993-1, 2009
ISO 10993-5, 2009
ISO 10993-7 2008
ISO 10993-10, 2010
ANSI/AAMI/ISO 11607-1, 2006
ANSI/AAMI/ISO 11135-1, 2007
ISO 14971, 2007
ISO 15223-1; 2012
IEC 60601-1: 2005
IEC 60601-2-2: 2009

Summary of Sterilization and Shelf Life Discussion

The Olympus - PK Needle is delivered in a sterile state and is intended for single patient use only. The sterilization method used is ethylene oxide and has a shelf life of three (3) years.

Summary of Performance Testing

The following performance tests were conducted:

- Dimensional Measurements
- Cutting equivalency to predicate
- Expected forces on devices
- Design feature testing (button activation)
- Shelf Life
- Sterilization
- Biocompatibility

Substantial Equivalence

The proposed Olympus – PK Needle has the same intended use, design, and scientific technology as the Predicate Everest Bipolar Needle Electrode (K031079). Both devices are of similar design and technology and have been shown to perform substantially equivalent in bench testing. There were no new issues of safety or effectiveness with the proposed device.

Conclusion:

In summary, the Olympus – PK Needle is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.