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

September 26, 2016

Gyrus ACMI Inc.
Mr. Graham Baillie
Regulatory Affairs Manager
136 Turnpike Road
Southborough, Massachusetts 01772

Re: K161825
Trade/Device Name: PK AIM
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 12, 2016
Received: September 13, 2016

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 Part 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 Parts 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" (21 CFR 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,

Christopher J. Ronk -S

For 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)*
K161825

Device Name
PK AIM

Indications for Use *(Describe)*
The PK AIM is intended for mono polar cutting & coagulation, grasping, bipolar coagulation of selected soft tissues and sealing vessels up to and including 3.0 mm in diameter during electro surgery. This device is not intended to be used for tubal ligation or female sterilization.

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
Gyrus ACMI, Inc.

Olympus PK AIM

General Information

Manufacturer:	Gyrus ACMI, Inc. 9600 Louisiana Ave North Brooklyn Park, MN 55445 Phone: 508-804-2690
Establishment Registration Number:	3011050570
510(k) Submitter:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Graham A. L. Baillie MS Regulatory Affairs Manager 508-804-2738 Graham.baillie@olympus-osta.com
Date Prepared:	June 27, 2016

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 AIM
Generic/Common Name:	Electrosurgical cutting and coagulation device

Predicate Devices

K152219 Olympus PK AIM

K081766 (Gyrus ACMI, Inc.) PKS OMNI Instrument

Comparison to Predicate Devices:

The Olympus PK AIM has been compared to predicate Olympus PK AIM and PKS OMNI with respect to intended use, design, and fundamental scientific technology. The comparisons and testing results presented in this 510(k) notification to FDA show this device to be substantially equivalent to predicate devices and raises no new concerns or safety or effectiveness.

Like the predicate PK AIM, the proposed PK AIM is intended for mono polar cutting and coagulation, grasping, bipolar coagulation of selected soft tissues, and like its predicate PKS OMNI the proposed PK AIM is also intended to seal vessels up to and including 3.0 mm in diameter during electro surgery. Both predicate and proposed PK AIM devices are not intended to be used for tubal ligation or female sterilization.

Product Description

Both predicate and proposed PK AIM devices can be described as 2 in 1 devices with a pencil type handle that combines the technologies of a monopolar pencil and a bipolar forceps. The device has buttons that allow hand activation and a sliding toggle switch to allow the surgeon to switch between a forceps, and a pencil device. Foot pedals connected to the generator are also available to allow for foot pedal activation of the device. 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 Olympus ESG-400 Generator.

The proposed device is comprised of a mixture of plastics, metals heatshrink and epoxy. The predicate Olympus PK AIM passed all applicable biocompatibility testing and additional information was provided within in K152219 for any patient contacting materials that contain colorants. The subject Olympus PK AIM and predicate Olympus PK AIM are physically identical – no design or material changes whatsoever.

Technological Characteristics

The proposed Olympus PK AIM uses monopolar energy in order to cut and bipolar energy in order to coagulate soft tissue in general surgical procedures. For safety and convenience the ESG-400 generator recognizes the proposed Olympus PK AIM when it is connected and limits generator settings to those dedicated for use with the proposed Olympus PK AIM device. These settings are called out in the IFU.

The Olympus PK AIM can be activated using buttons located on the device handle, or via a foot pedals which are sold separately. The hand activation allows the physician to activate either cut or coagulation (coag) mode without taking their eyes off the surgical site. A sliding toggle switch located on the handle allows the user to switch between using the device as a pencil or forceps.

Material

No material changes were made to the predicate PK AIM cleared under K152219.

Indications for Use

The PK AIM is intended for mono polar cutting & coagulation, grasping, bipolar coagulation of selected soft tissues and sealing vessels up to and including 3.0 mm in diameter during electro surgery. This device is not intended to be used for tubal ligation or female sterilization.

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

Like the predicate Olympus PK AIM, (K152219), the proposed Olympus PK AIM will be distributed 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 1 year.

Summary of Performance Testing

The predicate PK AIM (K152219) and proposed PK AIM, are identical in every respect. No physical design changes were made that would require the repeat of performance testing already provided in K152219. Bench and animal testing performance tests were conducted to support the additional 3 mm vessel sealing claim which is the subject of this submission. Performance testing provided in this submission will demonstrate that the 3 mm vessel sealing performance of the proposed PK AIM is substantially equivalent to the predicate Gyrus ACMI PKS OMNI, K081766.

The vessel sealing performance of subject PK AIM and the predicate PKS OMNI were compared via ex vivo bench testing, acute animal testing, and chronic animal testing (porcine model). Protocols, reports and test data for this testing are provided in the appendices of Section 15 and 16 and include:

Bench Testing ex vivo, confirmed that both devices:

- Sealed 1.00 mm to 3.49 mm size arteries.
- Burst pressures of sealed arteries were statistically equivalent.

- and burst pressure of sealed arteries exceeded 360 mmHg.

The Acute GLP Study evaluated thermal spread, qualitative sealing characteristics and provided collection of thermal imaging while sealing vessels with the Olympus PK AIM device in a swine model. The predicate Gyrus ACMI (PKS) OMNI device was used as the Control device. During the acute study, quantities of 11 and 12 blood vessels respectively were sealed by subject PK AIM and predicate PK OMNI. A Histopathology Report is attached to this study.

The Chronic GLP Study in a swine model evaluated thermal spread, qualitative sealing characteristics and provided a collection of thermal imaging while sealing vessels with the proposed Olympus PK AIM device. The predicate Gyrus ACMI (PKS) OMNI device was used as the Control device. The Chronic studies demonstrated that 11 animals survived a minimum of 21-days following the surgical procedure. Their health was deemed acceptable prior-to, during, and following the 21-day survival period at which time they were euthanized and grossly examined. A necropsy pathology of post-splenectomy and ovariectomy sealed vessel sites showed no differences between sealing performed by test and control devices.

The test results concluded that the subject PK AIM test article demonstrated similar functionality to the control article (Gyrus ACMI (PKS) OMNI) for sealing arteries, veins and artery vein bundles up to 3mm in diameter.

An Animal Health Report and Pathology Report were attached in the appendices of this report.

Substantial Equivalence

The proposed Olympus PK AIM has the same intended use, design, and scientific technology as its predicate Olympus PK AIM device combined into one device. The predicate PK AIM and proposed PK AIM device are both a pencil and a forceps device with a dual cord. The proposed and predicate devices were shown to perform substantially equivalent in bench testing. There were no new issues of safety or effectiveness with the proposed device. Please see the following Substantial

Equivalence Comparison Table:

Design Feature	**Proposed Olympus PK AIM**	**Predicate Olympus PK AIM K152219**	**Predicate PKS OMNI K081766**	**Comments**
Function of Device	Forceps/Pencil	Forceps/Pencil	Forceps	Same as predicate PK AIM
Tip Size	Forceps 1mm tip, 2mm base Pencil 2mm	Forceps 1mm tip, 2mm base Pencil 2mm		Same
Energy	Monopolar/Bipolar	Monopolar/Bipolar	Bipolar	Same

Activation	Hand / Footpedal	Hand / Footpedal		Same
Plug	Dual (mono/bi)	Dual (mono/bi)		Same
Electrode Materials	Stainless Steel	Stainless Steel		Same
Sterility	10^{-6} EtO	10^{-6} EtO	10^{-6} EtO	Same (10^{-6})
Single Use	Yes	Yes	Yes	Same
Intended Use	The PK AIM is intended for mono polar cutting & coagulation, grasping, bipolar coagulation of selected soft tissues and sealing vessels up to and including 3.0 mm in diameter during electro surgery. This device is not intended to be used for tubal ligation or female sterilization.	The PK AIM device is intended for monopolar cutting as well as grasping, manipulating and bipolar coagulation of selected soft tissues during electrosurgery. This device is not intended to be used for tubal ligation or female sterilization.	The Gyrus ACMI Inc. PKS OMNI Instruments is intended for electrosurgical coagulation, mechanical grasping, and dissection of tissue, and sealing of vessels up to 3mm, during the performance of laparoscopic and general (open) surgical procedures when used in conjunction with the Gyrus ACMI G400 Workstation.	Predicate and proposed PK AIM devices are the same except for the addition of 3 mm vessel sealing to the proposed PK AIM. The PKS OMNI was included as predicate because of its 3 mm vessel sealing.

Conclusion:

In summary, the proposed Olympus PK AIM is substantially equivalent to the predicate Olympus PK AIM and Gyrus ACMI PKS OMNI devices and presents no new questions of safety or efficacy.