December 12, 2016

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

Re: K163373
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: November 29, 2016
Received: December 1, 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 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" (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,

Jennifer R. Stevenson -A
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
Indications for Use

510(k) Number (if known)
K163373

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
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

Contact Person:
Graham A. L. Baillie
Manager, Regulatory Affairs
508-804-2738
Graham.baillie@olympus-osta.com

Date Prepared: November 29, 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
Trade Name: Olympus PK Aim
Generic/Common Name: Electrosurgical cutting and coagulation
device

Predicate Device
K161825

Comparison to Predicate Device:
The Olympus PK AIM has been compared to the predicate Olympus PK AIM with
respect to intended use, design and fundamental scientific technology. The
comparisons and summary of testing results presented in this Special 510(k)
Notification show this device to be substantially equivalent to the predicate PK AIM
and raises no new concerns of safety or effectiveness.

Like the predicate PK AIM, the proposed PK AIM is intended for monopolar cutting
and coagulation, grasping, bipolar coagulation of selected soft tissue, and like its
predicate PK AIM the proposed device is also intended to seal vessels up to and
including 3.0 mm in diameter during electrosurgery. 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 electrosurgical system. The instrument is to be used only with the Olympus ESG-400 Generator. As a result of the PK AIM cable modifications which are the subject of this submission, no modifications were required or made to the 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 the original PK AIM K152219 for any patient contacting materials that contain colorants. Except for the cable design modification that is being implemented to address a capacitive coupling concern, the subject Olympus PK AIM and predicate Olympus PK AIM are physically identical – no other design or material changes.

**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 monopolar pencil or bipolar forceps.

**Material**

No material or packaging changes were made to the predicate PK AIM cleared under K161825.

**Indications for Use**

The intended use of the modified/proposed PK AIM device, as described in its labeling, has not changed as a result of the cable modification.

The PK AIM is intended for monopolar 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 Olympus PK AIM 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
- 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, (K161825), the proposed Olympus PK AIM will be distributed in a sterile state and is intended for single patient use only. The sterilization method used continues to be ethylene oxide and will now be labeled with a shelf life of 3 years.

Summary of bench, Performance Testing (no clinical testing was conducted)

<table>
<thead>
<tr>
<th>Description</th>
<th>Specification/objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cable/Cord Length</td>
<td>Meet length specification</td>
</tr>
<tr>
<td>Electrical Functionality</td>
<td>Generator confirmation</td>
</tr>
<tr>
<td>Package Testing</td>
<td>ISTA-2A, ASTMD4169-09</td>
</tr>
<tr>
<td>IEC 60601</td>
<td>Meet relevant requirements</td>
</tr>
<tr>
<td>Label/Package damage</td>
<td>Visual inspection</td>
</tr>
<tr>
<td>Bubble Leak</td>
<td>ASTM-F2906-11</td>
</tr>
<tr>
<td>Continuity</td>
<td>Meet specification</td>
</tr>
<tr>
<td>Hi-Pot</td>
<td>Meet specification</td>
</tr>
<tr>
<td>HF Leakage</td>
<td>Meet monopolar HF leakage from bipolar electrodes</td>
</tr>
<tr>
<td>Electrical Characterization</td>
<td>Meet internal comparable power outputs</td>
</tr>
</tbody>
</table>

All performance testing passed or met prescribed acceptance criteria

Substantial Equivalence

The proposed Olympus PK AIM has the same intended use, scientific technology and similar design as its predicate Olympus PK AIM 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.
Equivalence Comparison Table:

<table>
<thead>
<tr>
<th>Design Feature</th>
<th>Proposed Olympus PK AIM</th>
<th>Predicate Olympus PK AIM K161825</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function of Device</td>
<td>Forceps/Pencil</td>
<td>Forceps/Pencil</td>
<td>Same as predicate PK AIM</td>
</tr>
<tr>
<td>Tip Size</td>
<td>Forceps 1mm tip, 2mm base Pencil 2mm</td>
<td>Forceps 1mm tip, 2mm base Pencil 2mm</td>
<td>Same</td>
</tr>
<tr>
<td>Energy</td>
<td>Monopolar/Bipolar</td>
<td>Monopolar/Bipolar</td>
<td>Same</td>
</tr>
<tr>
<td>Activation</td>
<td>Hand / Footpedal</td>
<td>Hand / Footpedal</td>
<td>Same</td>
</tr>
<tr>
<td>Plug</td>
<td>Dual (mono/bi)</td>
<td>Dual (mono/bi)</td>
<td>Same</td>
</tr>
<tr>
<td>Electrode Materials</td>
<td>Stainless Steel</td>
<td>Stainless Steel</td>
<td>Same</td>
</tr>
<tr>
<td>Sterility</td>
<td>$10^6$ EtO</td>
<td>$10^6$ EtO</td>
<td>Same</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
<td>Same</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The PK AIM is intended for mono polar cutting &amp; coagulation, grasping, bipolar coagulation of selected soft tissues and sealing vessels up to and including 3.0 mm in diameter during electrosurgery. This device is not intended to be used for tubal ligation or female sterilization.</td>
<td>The PK AIM is intended for mono polar cutting &amp; coagulation, grasping, bipolar coagulation of selected soft tissues and sealing vessels up to and including 3.0 mm in diameter during electrosurgery. This device is not intended to be used for tubal ligation or female sterilization.</td>
<td>Predicate and proposed PK AIM devices have identical intended uses.</td>
</tr>
</tbody>
</table>

**Conclusion:**

In summary, the Olympus PK AIM is substantially equivalent to its predicate device and presents no new questions of safety or efficacy.