May 19, 2017

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

Re: K170908
   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: March 27, 2017
   Received: March 28, 2017

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 -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
Indications for Use

510(k) Number (if known)
K170908

Device Name
PK AIM

Indications for Use (Describe)
The PK AIM is indicated for open, general surgery (including plastic and re-constructive) or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping and dissection is performed. The device has been designed to seal and cut vessels (up to and including 3 mm in diameter), tissue bundles, and lymphatics when used with the Olympus ESG-400 Generator. This device is not intended to be used for tubal ligation or female sterilization.

Type of Use (Select one or both, as applicable)
- [x] 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:

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

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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: March 27, 2017

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
K163373 Olympus PK AIM
K151743 Olympus Open Fine Jaw (OFJ)

Comparison to Predicate Devices:
The Olympus PK AIM (Plasma Kinetic Advanced Integrated Multifunctional Device) has been compared to predicate Olympus PK AIM and Olympus Thunderbeat Open Fine Jaw (TB OFJ) 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 also intended for monopolar cutting and coagulation, grasping, bipolar coagulation of selected soft tissues, and to seal vessels up to 3.0 mm in diameter during electro surgery. The proposed PK AIM will also carry additional indications currently cleared by K151743 - the Olympus Open Fine Jaw (OFJ). The sole purpose of this submission is to expand the PK AIM intended use to include “…open, general surgery (including plastic and reconstructive) “tissue bundles, and lymphatics.” Both predicate OFJ and proposed PK AIM devices are not intended to be used for tubal ligation or female sterilization.

**Product Description**

Both predicate PK AIM 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. Both predicates (Olympus OFJ and Olympus PK AIM connect/plug into the Olympus ESG-400 generator (K141225). The generator and subject device make up a medical electrical system. The PK AIM 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 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 have been made to patient contacting surfaces. 

**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 model PK-AI2055 cleared most recently under K163373.
Indications for Use
The PK AIM is indicated for open, general surgery (including plastic and re-constructive) or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping and dissection is performed. The device has been designed to seal and cut vessels (up to and including 3 mm in diameter), tissue bundles, and lymphatics when used with the Olympus ESG-400 Generator. This device is not intended to be used for tubing ligation or female sterilization.

Compliance to Voluntary Standards
The design of the proposed PK AIM device continues to comply 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 (K163373), 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 3 years. Sterilization method and shelf life remain identical to the predicate PK AIM.

Summary of Performance Testing
The predicate PK AIM (K163373) and proposed PK AIM are identical in every respect. No physical design changes were made to the handle or distal grasping forceps and monopolar components that would require the repeat of performance testing already provided in the original PK AIM, K152219. Performance of the proposed PK AIM is substantially equivalent to the predicate PK AIM.

Bench (tissue testing) and animal (lymphatic sealing) studies described below were conducted by American Preclinical Services (APS) in support of the desired additional indications.

Lymphatic Sealing: An acute GLP study was conducted to assess the lymphatic sealing performance of the proposed PK Advanced Integrated Multifunctional Device as compared to the predicate THUNDERBEAT Open Fine Jaw in a healthy porcine model. The study was conducted by APS located in Minneapolis, MN. The control article (predicate) was the THUNDERBEAT Open Fine Jaw (TB OFJ). The OFJ is an Ultrasonic and bipolar energy seal and cut device (K151743) for cut and coagulation of tissue. One animal underwent multiple lymphatic vessel seals. 15 mesenteric lymph vessels were sealed with the test device and 16 mesenteric lymph vessels were sealed.
with the control device. The study surgeon evaluated each seal immediately post seal and then again 30 seconds to one minute post seal.

The surgeon evaluated each vessel seal for integrity, tissue sticking, and char. All vessels sealed with the proposed PK AIM test article had no tissue sticking and no charring. All vessel seals had no leakage of lymph and had complete hemostasis immediately and at 30 seconds to one minute post seal. All vessels sealed with the OFJ control article had no tissue sticking and no charring. All vessel seals had no leakage of lymph and had complete hemostasis immediately and at 30 seconds to one minute post seal. All study endpoints were met. The proposed PK AIM test article performed equivalent to the predicate OFJ control article as evaluated by the study surgeon per section 3.3.1 of the study protocol. All sealed lymph vessels were sealed immediately with no lymph leakage and remained sealed at the 30 seconds to one minute time point.

Bench/ex-vivo tissue study

APS conducted a GLP ex-vivo study to evaluate tissue effect performance of the Olympus PK AIM device and the predicate Olympus OFJ. The purpose of the study was to compare tissue changes between the PK AIM device and the OFJ in ex-vivo swine liver, swine kidney and bovine cardiac muscle tissue.

Bench Ex Vivo Design Verification testing demonstrated that the requirements defined in the protocol were met. This bench ex vivo tissue test data confirms that the proposed PK AIM tissue performance is substantially equivalent to the predicate Olympus Thunderbeat OFJ.

Substantial Equivalence

The proposed Olympus PK AIM has the identical design, materials, packaging and scientific technology 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 that provides mono and bipolar energy from the same Olympus ESG-400 Generator.

The predicate and proposed PK AIM devices are physically identical and will only differ with the addition of indications carried by the predicate Olympus OFJ. The OFJ was included as a predicate because of its similar Bipolar/RF technology generated by the same Olympus ESG-400 Generator and because it carries the additional indications desired for the proposed PK AIM that include: “open, general surgery (including plastic and re-constructive) tissue bundles and lymphatics.”

Please refer to the following Substantial Equivalence Comparison Table:

<table>
<thead>
<tr>
<th>Design Feature</th>
<th>Proposed Olympus PK AIM</th>
<th>Predicate Olympus PK AIM K163373</th>
<th>Predicate Thunderbeat OFJ K151743</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function of Device</td>
<td>Forceps/Pencil</td>
<td>Forceps/Pencil</td>
<td>Hemostat style body</td>
<td>Identical to Predicate PK AIM</td>
</tr>
<tr>
<td>Tip Size</td>
<td>Forceps: 1mm tip, 2mm tip, 3mm base</td>
<td>Forceps: 1mm tip, 2mm tip, 3mm base</td>
<td></td>
<td>Identical to</td>
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<tr>
<td>Design Feature</td>
<td>Proposed Olympus PK AIM</td>
<td>Predicate Olympus PK AIM K163373</td>
<td>Predicate Thunderbeat OFJ K151743</td>
<td>Comments</td>
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<tr>
<td>Energy</td>
<td>Monopolar/Bipolar</td>
<td>Monopolar/Bipolar</td>
<td>Bipolar/ultrasonic</td>
<td>In Seal mode the OFJ uses only bipolar energy from the ESG-400 to enable vessel, tissue bundle and lymphatic sealing and hemostasis</td>
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<tr>
<td>Activation</td>
<td>Hand / Footpedal</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>Bipolar/ultrasonic</td>
<td>Identical to Predicate PK AIM. Same RF source.</td>
</tr>
<tr>
<td>Electrode Materials</td>
<td>Stainless Steel</td>
<td>Stainless Steel</td>
<td>Grasping section: PTFE/Aluminum Probe: Ti6AI-4V</td>
<td>PK AIM matls are identical OFJ are similar</td>
</tr>
<tr>
<td>Sterility</td>
<td>SAL 10⁰ EtO</td>
<td>SAL 10⁰ EtO</td>
<td>SAL 10⁰ EtO</td>
<td>Identical</td>
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<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Identical</td>
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<tr>
<td>Intended Use</td>
<td>The PK AIM is indicated for open, general surgery (including plastic and re-constructive) or in any procedure in which cutting, vessel ligation (sealing and cutting), coagulation, grasping and dissection is performed. The device has been designed to seal and cut vessels (up to and including 3 mm in diameter), tissue bundles, and lymphatics. This device is not intended to be used for tubal ligation or female sterilization.</td>
<td>The PK AIM is intended for monopolar cutting &amp; 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.</td>
<td>THUNDERBEAT Open Fine Jaw hand instrument when used in combination with the Seal &amp; Cut mode is indicated for open, general surgery (including plastic and reconstructive, etc.) or in any procedure</td>
<td>Predicate and proposed PK AIM devices are the same except for the addition of indications carried by the predicate OFJ. The OFJ was included as a predicate because of its similar technology and it carries additional indications that include: open, general surgery (including plastic and re-constructive) tissue bundles</td>
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<tr>
<td>Design Feature</td>
<td>Proposed Olympus PK AIM</td>
<td>Predicate Olympus PK AIM K163373</td>
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<td>in which cutting, vessel ligation (sealing and cutting), coagulation, grasping, and dissection is performed. The device has been designed to seal and cut vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.</td>
<td>and lymphatics.</td>
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<td>This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, and tonsillectomy) for only ligation (sealing and cutting) of vessels, lymphatics and tissue bundles 2-3mm*1 away from unintended thermally sensitive structures such as nerves and parathyroid glands.</td>
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<td>Seal mode: The THUNDERBEAT Open Fine Jaw hand instrument when used in combination with the Seal mode is indicated for open, general surgery (including plastic and reconstructive, etc.) or in any procedure in which vessel sealing, coagulation, grasping is performed. The</td>
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<tr>
<td>Design Feature</td>
<td>Proposed Olympus PK AIM</td>
<td>Predicate Olympus PK AIM K163373</td>
<td>Predicate Thunderbeat OFJ K151743</td>
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</table>

Device has been designed to seal vessels (up to and including 7 mm in diameter), tissue bundles, and lymphatics.

This mode is also indicated for open ENT procedure in adults (thyroidectomy, parathyroidectomy, parotidectomy, and tonsillectomy) for sealing of vessels, lymphatics and tissue bundles 2-3 mm*1 away from unintended thermally sensitive structures such as nerves and parathyroid glands.

The THUNDERBEAT Open Fine Jaw hand instrument has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

*1 It should be extended appropriately depending on the operation situation.

**Conclusion:**

In summary, bench testing confirmed that the proposed Olympus PK AIM is substantially equivalent to the predicate Olympus PK AIM and Olympus OFJ devices and presents no new questions of safety or efficacy.