January 4, 2022

Dolan Mills
Program Manager, Regulatory Affairs
Gyrus ACMI, Inc.
9600 Louisiana Ave. North
Brooklyn Park, MN 55445
USA

Re: K213831
Trade/Device Name: Olympus PK Electrosurgical Instruments: PK Needle, PK Spatula, PK J-hook
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 7, 2021
Received: December 8, 2021

Dear Dolan Mills:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213831

Device Name
Olympus PK Electrosurgical Instruments:
PK Needle, PK Spatula, PK J-Hook

Indications for Use *(Describe)*
1. The PK Needle is indicated for resection of soft tissue in laparoscopic and general surgical procedures.

2. The PK Spatula is indicated for resection and coagulation of soft tissue and blood vessels in laparoscopic and general surgical procedures.

3. The PK J-Hook is indicated for resection and coagulation of soft tissue and blood vessels in laparoscopic and general surgical procedures.

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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K213831
510(k) Summary
Gyrus ACMI, Inc.
Olympus PK Electrosurgical Instruments

Date Prepared: Dec 22, 2021

General Information

Manufacturer: Gyrus ACMI, Inc.
9600 Louisiana Blvd. North
Brooklyn Park, MN 55455
USA

Establishment Registration Number: 3011050570

Contact Person: Dolan Mills
Program Manager, Regulatory Affairs
901-355-0007
Dolan.mills@olympus.com

Device Description

Proprietary names:	Olympus PK Electrosurgical Instruments: PK Needle, PK Spatula, PK J-Hook
Device Classification Name:	Electrosurgical Cutting and Coagulation device and Accessories
Regulations number:	21 CFR 878.4400
Regulation Medical Specialty:	General and Plastic Surgery
Regulatory Class:	Class II
Product Code:	GEI
Generic/Common Name:	Electrosurgical Cutting and Coagulation device and Accessories

Predicate Devices

The Olympus PK Electrosurgical Instruments: PK Needle (model # PK-NE0533), PK Spatula (model # PK-SP0533), and PK J-Hook (model # PK-JH0533), were cleared under K142154 (PK Needle), K142289 (PK Spatula), and K142350 (PK J-Hook). This submission is a modification to the device labeling to add compatibility with an Olympus generator, ESG-410 cleared under K203277.

The predicate device has not been subject to any recalls.

Product Description

PK-NE0533: 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 device plugs into the Olympus ESG-400 generator (K141225), and the Olympus ESG-410 generator (K203277). The generator and device make up a medical electrical system. The instrument is to be used only with the compatible Generators.

PK-SP0533: The PK Spatula is a bipolar electrosurgical instrument with the capability to cut and coagulate soft tissue and blood vessels in laparoscopic and general surgery. The instrument will pass through a 5mm cannula or through an operating laparoscope working channel of 5mm or larger diameter. The instrument is used with a 5 way connector cable. The device is intended for use in a non-irrigated (dry) environment. The device plugs into the Olympus ESG-400 generator (K141225), and the Olympus ESG-410 generator (K203277). The generator and device make up a medical electrical system. The instrument is to be used only with the compatible Generators.

PK-JH0533: The PK J-Hook is a bipolar electrosurgical instrument with the capability to cut and coagulate soft tissue and blood vessels in laparoscopic and general surgery. 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 “J” shaped tip and is activated via buttons on the handle, or by a foot pedal. The device plugs into the Olympus ESG-400 generator (K141225), and the Olympus ESG-410 generator (K203277). The generator and device make up a medical electrical system. The instrument is to be used only with the compatible Generators.

The device is compliant with FDA recognized consensus safety standards as listed below.

Technological Characteristics

The Olympus PK Electrosurgical Instruments are unchanged from the original clearance in terms of intended use, design, performance, and technological characteristics. The only difference is in the labeling that identifies an additional compatible Olympus generator.

For safety and convenience the compatible generator recognizes and automatically presets the default output settings once the instrument is connected.

The PK Needle is activated using a button located on the device handle, or via a foot pedal. The device is a bipolar electrosurgical instrument with the capability to resect soft tissue and blood vessels in laparoscopic and general surgical procedures. The active tip is exposed in a blunt "needle" like electrode tip which is the active portion of the device allowing for cutting.

The PK Spatula is activated using buttons located on the device handle. This allows the physician to activate either cut or coagulation (coag) mode without taking their eyes off the surgical site. Historically foot pedals have been used for such devices and are also available for the proposed device. A nosecone located at the distal end of the handle and at the proximal end of the device shaft allows the physician to alter the orientation of the electrode tip without altering the orientation of the handle.

The PK J-Hook is activated using buttons located on the device handle, or via a foot pedal. This allows the physician to activate either cut or coagulation (coag) mode without taking their eyes off the surgical site. A nosecone located at the distal end of the handle and at the proximal end of the device shaft allows the physician to alter the orientation of the electrode tip without altering the orientation of the handle.

Material

The materials have not changed for these devices since their original clearance, in which full biocompatibility information was provided.

Indications for Use

1. The PK Needle is indicated for resection of soft tissue in laparoscopic and general surgical procedures.

2. The PK Spatula is indicated for resection and coagulation of soft tissue and blood vessels in laparoscopic and general surgical procedures.

3. The PK J-Hook is indicated for resection and coagulation of soft tissue and blood vessels in laparoscopic and general surgical procedures.

Compliance to Voluntary Standards

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

Standards Number	Standard Title	FDA Recognition no + date
AAMI/ANSI ES 60601-1:2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	19-4 07/09/2014
IEC 60601-2-2 Ed.	Medical electrical equipment - Part 2-2: Particular	6-389

6.0:2017-03	requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	08/21/2017
ANSI AAMI ISO 14971 2019	Medical devices – Application of risk management to medical devices	5-125 12/23/2019
ISO 11135: 2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices	14-529 07/15/2019
ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1 General requirements	5-117 08/21/2017
ISO 11607-1 Second Edition 2019-2	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	14-530 07/15/2019
ISO 10993-1:2018	Biological Evaluation of Medical Devices, Part 1: Evaluation and testing within a risk management process	2-258 01/14/2019
ISO 10993-5:2009	Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity	2-245 12/23/2016
ISO 10993-10:2010	Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization	2-174 07/26/2016
ISO 10993-7 Second Edition 2008-10-15	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	14-408 01/30/2014

Summary of Sterilization and Shelf Life Discussion

The product and packaging materials as well as the sterilization mode has not changed since the original clearance, therefore no additional testing was needed.

Summary of Performance Testing

Non-clinical testing was conducted as part of demonstrating substantial equivalence to the predicate device and to ensure that the performance criteria was met when used with the additional compatible generator. A risk analysis was completed to identify any new risks associated with the update. The following tests associated with the device modification were performed on the subject device according to the methods and acceptance criteria established in the original clearances noted above:

- Non-clinical (electrical, mechanical, functional, generator compatibility, cutting equivalency to predicate)

Comparison to Predicate Discussion

The Olympus PK Electrosurgical Instruments have identical clinical indications for use as the previously cleared devices. There have been no changes in the devices as compared to the previously cleared devices in K142154, K142289, and K142350. The

only difference is the compatibility with an additional cleared Olympus generator, ESG-410. The labeling has been updated to reflect this additional compatible generator.

Conclusion:

In summary, the Olympus PK Electrosurgical Instruments are equivalent to the predicate devices and present no new questions of safety or effectiveness.