May 15, 2019

Olympus Medical Systems Corp.
Daphney Germain-Kolawole
Senior Project Manager, Regulatory Affairs
Olympus Surgical Technologies America
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610

Re: K182408
Trade/Device Name: Single Use Electrosurgical Knife KD-625, Single Use Electrosurgical Knife KD-645
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: March 25, 2019
Received: March 26, 2019

Dear Daphney Germain-Kolawole:

This letter corrects our substantially equivalent letter of May 15, 2019.

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Shani Haugen
Acting Assistant Division Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182408

Device Name
Single Use Electrosurgical Knife KD-625, Single Use Electrosurgical Knife KD-645

Indications for Use *(Describe)*

KD-625

These instruments have been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue using high-frequency current within the digestive tract.

These instruments are indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope.

KD-645

This instrument has been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue using high-frequency current within the digestive tract.

This instrument is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope.

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:

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"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."

Date Prepared: March 25, 2019

510(k) Summary

5.1 GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
192-8507

■ Contact Person: Daphney Germain-Kolawole
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3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-5691
Fax: 484-896-7128
Email: daphney.germain-kolawole@olympus.com

■ Manufacturing site: 2-248-1 Okkonoki, Kuroishi-shi, Aomori 036-0357, Japan

5.2 DEVICE IDENTIFICATION

■ Device Name: Single Use Electrosurgical knife KD-625
Single Use Electrosurgical knife KD-645

■ Common Name: Single Use Electrosurgical knife

■ Regulation Number: 876.4300

■ Regulation Name: Endoscopic electrosurgical unit and accessories

■ Regulatory Class: II

■ Product Code: KNS

5.3 PREDICATE DEVICE

1) Predicate device

Table 12-1 Predicate device on KD-625 and KD-645

Device name	510(k) Submitter	510(k) No.
Single Use Electrosurgical knife KD-655	OLYMPUS MEDICAL SYSTEMS CORP.	K171158

2) Reference device

Table 12-2 Reference device on KD-625

Device name	510(k) Submitter	510(k) No.
KD-620LR (Single Use Electrosurgical Knife Series)	OLYMPUS MEDICAL SYSTEMS CORP.	K092309

Table 12-3 Reference device on KD-645

Device name	510(k) Submitter	510(k) No.
KD-640L (Single Use Electrosurgical Knife Series)	OLYMPUS MEDICAL SYSTEMS CORP.	K092309

5.4 DEVICE DESCRIPTION

1) General Description of the subject device

These instruments have been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue using high-frequency current within the digestive tract. These instruments are indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope.

This system consists of the electrosurgical knives (subject devices), flushing pump, and water tubes (accessories). The subject devices are indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope. They will be marketed as sterilized (ETO) devices for single use.

2) Principle of Operation

The subject devices are used in combination with an endoscope and electrosurgical generator to resect a lesion in the gastrointestinal tract using high frequency current. The KD-625 and KD-645 are composed of a handle and insertion portion. The insertion portion is inserted into the gastrointestinal organ via an endoscope.

The subject devices are connected to an electrosurgical unit through the electrode on the handle and the A cord. The electrode is electrically connected with the cutting knife through a wire, which allows cutting using electricity supplied from the electrosurgical unit. Pushing the slider of the handle allows the insertion portion to follow the slider movement and allows the cutting knife at the distal end to extend. Holding the extended cutting knife against the target tissue enables dissection of the tissue.

In addition, the subject devices can supply fluid into the submucosa in combination with a flushing device. Saline solution is supplied, via the channel inside the sheath, from the nozzle at the distal end through a water tube or flushing device connected to the accessory port on the handle.

5.5 INDICATIONS FOR USE

5.5.1 INDICATIONS FOR USE for KD-625

These instruments have been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue using high-frequency current within the digestive tract. These instruments are indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope.

5.5.2 INDICATIONS FOR USE for KD-645

This instrument has been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue using high-frequency current within the digestive tract. This instrument is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope.

5.6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The Single Use Electrosurgical Knife KD-625 and KD-645 have the same technological characteristics and design as the predicate device except for the following new features:

- Material and shape of the cutting knife
- Shape of the water outlet

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side-by-side comparison of the subject devices and the predicate device is provided below.

Item	<Subject Device> KD-625	<Subject Device> KD-645	<Predicate Device> KD-655 (#171158)
Indications for use	These instruments have been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue using high-frequency current within the digestive tract. These instruments are indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope.	This instrument has been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue using high-frequency current within the digestive tract. This instrument is indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope.	These instruments have been designed to be used with Olympus endoscopes and electrosurgical units to cut tissue within the digestive tract and using high-frequency current. These instruments are indicated for the induction of sterile normal saline into the submucosa to lift mucosal lesions using direct visualization through an endoscope.
Common name	Single Use Electrosurgical knife	Single Use Electrosurgical knife	Single Use Electrosurgical knife
Regulation number	876.4300	876.4300	876.4300

Item	<Subject Device> KD-625	<Subject Device> KD-645	<Predicate Device> KD-655 (#171158)
Regulation name	Endoscopic electrosurgical unit and accessories	Endoscopic electrosurgical unit and accessories	Endoscopic electrosurgical unit and accessories
Regulatory class	II	II	II
Classification panel	Gastroenterology and urology	Gastroenterology and urology	Gastroenterology and urology
Product code	KNS	KNS	KNS
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital	Healthcare facility/hospital
Single/repeat use	Single-use	Single-use	Single-use
Sterile/non-sterile	Marketed as a sterilized device	Marketed as a sterilized device	Marketed as a sterilized device
Sterilization method	ETO sterile	ETO sterile	ETO sterile
Energy source	High-frequency current	High-frequency current	High-frequency current
Material composition of main patient-contact parts	Stainless steel Ceramics ABS PTFE Silicone Rubber	Stainless steel Ceramics ABS PTFE Silicone Rubber	Stainless steel Ceramics ABS PTFE Silicone Rubber
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).

5.7 PERFORMANCE DATA

The following performance data are being provided in support of the substantial equivalence determination.

1) Sterilization/Shelf-life testing

Sterilization/shelf-life testing for the Single Use Electrosurgical Knife KD-625 and KD-645 were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile".

Accelerated aging test for the subject devices were conducted in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. The real-time aging test for three years will be performed to demonstrate longer stability and support the results of the accelerated aging test.

2) Biocompatibility testing

Biocompatibility testing for the subject devices were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity Study Using the Colony Assay
- Intracutaneous Study in Rabbits
- Guinea Pig Maximization Sensitization Test
- Systemic Toxicity Study in Mice
- USP Rabbit Pyrogen Study, Material Mediated

3) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject devices. The system complies with the AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2 Edition 3: 2007 standards for EMC.

4) Performance testing - Bench

Bench testing for the subject devices as listed below was conducted to ensure that the subject device performs as intended and meet design specifications. Device performance was assessed according to the design requirements and included process verification, design verification, and design validation.

- Evaluation Test for Performance to Cut Digestive Tract Mucosa
- Evaluation Test for Lifting of Digestive Tract Mucosa
- Histopathological Evaluation Test of Thermal Damage on Digestive Tract
- Evaluation Test for safety against perforation by saline feeding function

5) Risk analysis

Risk analysis for the subject devices were conducted in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

5.8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the subject devices raise no new issue of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, efficacy and performance.