DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 1, 2016

Olympus Medical Systems Corp.
% Daphney Germain-Kolawole
Project Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610

Re: K160241
Trade/Device Name: Single Use Sphincterotome V (Distal Wireguided)
KD-VC412Q-0215
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: January 29, 2016
Received: February 1, 2016

Dear Daphney Germain-Kolawole,

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 yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*

K160241

Device Name
Single Use Sphincterotome V(Distal Wireguided) KD-VC412Q-0215

Indications for Use *(Describe)*
This instrument has been designed to be used with an Olympus endoscope and guidewire for papillotomy using high-frequency current.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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510(k) SUMMARY

Single Use Sphincterotome V(Distal Wireguided)
KD-VC412Q-0215

January 29, 2016

5.1 General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
  Establishment Registration No: 8010047

- Official Correspondent: Daphney Germain-Kolawole
  Project Manager, Regulatory Affairs
  Olympus Corporation of the Americas
  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

- Manufacturer: Aomori Olympus Co., Ltd.
  2-248-1 Okkonoki , Kuroishi-shi, Aomori, 036-0357, Japan
  Establishment Registration No.: 9614641

5.2 Device Identification

- Device Trade Name: Single Use Sphincterotome V(Distal Wireguided)
  KD-VC412Q-0215
- Common Name: Sphincterotome
- Regulation Number: 876.4300
- Regulation Name: Endoscopic electrosurgical unit and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: KNS

5.3 Predicate Device Information

Single Use Sphincterotome V(Distal Wireguided)		
Model name	Applicant	510(k) No.
Single Use Sphincterotome V	OLYMPUS MEDICAL SYSTEMS CORP.	K141991

5.4 Device Description

The subject device consists of the papillotomy knife for endoscopic sphincterotomy. The subject device consists of a partially open guidewire lumen. The partially open guidewire lumen is called the C-Channel design. The subject device is a variation of the predicate device.

5.5 Indications for Use

This instrument has been designed to be used with an Olympus endoscope and guidewire for papillotomy using high-frequency current.

5.6 Comparison of Technological Characteristics

Compared to the predicate device, the subject sphincterotome is different from the predicate device in the following five points on the distal end, on the shelf-life, and tube fixation to the guidewire port mold. This change of the distal end is to meet user's preference. The other features are identical to the predicate device.

- Difference on the distal end
  - Tip length
  - Knife length
  - Addition of notches
  - Removal of 8 mm marker
  - Removal of radiopaque marker

- Shelf-life is extended to three years

- Tube fixation to the guidewire port mold

5.7 Summary of non-clinical testing

Risk analysis was carried out 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.

Shelf-life of three years have been confirmed by accelerated aging test in accordance with ASTM F-1980-07.

5.8 Conclusion

When compared to the predicate device, the Single Use Sphincterotome V(Distal Wireguided) KD-VC412Q-0215 does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.