December 7, 2017

Olympus Medical Systems Corp.
% Sheri L. Musgnung
Regulatory Affairs Manager
Olympus Corporation of the Americas
3500 Corporate Parkway P.O. Box 610
Center Valley, PA 18034-0610

Re: K172734
Trade/Device Name: Single Use Electrosurgical Snare SD-400
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: FDI, FGX
Dated: November 14, 2017
Received: November 15, 2017

Dear Sheri L. Musgnung:

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.

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.

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,

Benjamin R. Fisher -S

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)*
K172734

Device Name
Single Use Electrosurgical Snare SD-400

Indications for Use *(Describe)*
These instruments have been designed to be used with an Olympus endoscope for the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

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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510(k) Summary

September 8,2017

I. General Information

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

- Official Correspondent: Sheri L. Musgnung
  Manager, Regulatory Affairs
  Olympus Corporation of the Americas
  3500 Corporate Parkway PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-3147
  FAX: 484-896-7128
  Email: sheri.musgnung@olympus.com

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

II. Device Identification

- Device Trade Name: Single Use Electrosurgical Snare SD-400
- Common Name: Snares
- Regulation Number: 876.4300
  876.4730
- Regulation Name: Endoscopic electrosurgical unit and accessories
  Manual gastroenterology-urology surgical instrument and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: FDI
  FGX
- Classification Name snare, flexible
  snare, non-electrical

III. Predicate Device and Reference Devices Information

Single Use Electrosurgical knife		
Predicate Device		
Device name	Applicant	510(k)#
CAPTIVATOR II,SINGLE-USE POLYPECTOMY SNARES	Boston Scientific Corporation	K133987

IV. Device Description

The subject device is designed to be used with an Olympus endoscope for the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

The subject device consists of a handle section, a tube section and a loop section. The loop section is inserted into the tube section and is extended and retracted by operating the handle section.

The tube section and the loop section are inserted into the gastrointestinal tract through the endoscope. The loop is extended from the tube to resect the target tissue. The resection is performed with or without high-frequency current.

V. Indications for Use

These instruments have been designed to be used with an Olympus endoscope for the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

VI. Comparison of Technological Characteristics

Compared to the predicate devices, the proposed subject device, Single Use Electrosurgical Snare SD-400 has similar technological characteristics except for the following differences.

- Shape of the snare loop
- Maximum insertion portion diameter
- Lineup (Loop width)
- Diameter of the snare loop wire

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 device and the predicate device is provided below.

Item	<Subject Device> Single Use Electrosurgical Snare SD-400	<Predicate Device> CAPTIVATOR II, SINGLE-USE POLYPECTOMY SNARES (K133987)
Indications for use	These instruments have been designed to be used with an Olympus endoscope for the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.	The Polypectomy Snares are used endoscopically in the removal and /or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.
Common name	Snares	Polypectomy Snare
Regulation number	876.4300 876.4730	876.4300 876.4730
Regulation name	Endoscopic electrosurgical unit and accessories Manual gastroenterology-urology surgical instrument and accessories	Endoscopic electrosurgical unit and accessories Manual gastroenterology-urology surgical instrument and accessories
Regulatory class	II	II
Classification panel	Gastroenterology and Urology	Gastroenterology and Urology
Product code	FDI FGX	FDI FGX
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital
Single/repeat use	Single-Use	Single-Use
Sterile/non-sterile	Marketed as a sterile device	Marketed as a sterile device
Sterilization method	ETO sterile	ETO sterile
Energy source	With or without High-frequency current	With or without High-frequency current

Item	<Subject Device> Single Use Electrosurgical Snare SD-400	<Predicate Device> CAPTIVATOR II, SINGLE-USE POLYPECTOMY SNARES (K133987)
General type of materials	Composed of ABS (handle section), fluorocarbon polymer (tube section), and stainless steel (loop section). The materials used in the device do not conform to an FDA recognized consensus standard for medical use.	Unknown
Patient-contact potential (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).	Same as subject device
Coatings/additives	Silicone oil is used as coating on the part of the loop section. No additives are applied to patient contact materials.	Unknown

VII. Summary of non-clinical testing

Performance testing was conducted on the following items to support the marketing claims and to confirm that the safety and effectiveness of the Single Use Electrosurgical Snare SD-400 is at least equivalent to the predicate device.

- Snare operation with the compatible endoscopes
- Dimensions of each part of the snare
- Durability of snare loop wire

The EO residual and ECH residual were measured after sterilization of the device to meet the criteria defined in ISO 11135 Second edition 2014 and AAMI/ANSI/ISO 10993-7:2008(R)2012.

The shelf-life for three years had been validated in accelerated testing according to ASTM F1980-16 (2016) and the requirements on packaging for terminally sterilized medical device per AAMI/ANSI/ISO 11607-1:2006/(R) 2010 and AAMI/ANSI/ISO 11607-2:2006/(R)2010 are also met. The testing successfully demonstrated essential performance is achieved before and after the shelf life test.

Biocompatibility testing was performed in accordance with the FDA Guidance," Use of International Standard ISO-10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on June 16, 2016. The cytotoxicity, sensitization, intracutaneous irritation and system toxicity tests were performed to demonstrate the biocompatibility of the device.

Tests on Electromagnetic Compatibility and Electrical Safety were performed in accordance to requirements per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-1-2 Edition 3: 2007-03, and in particular we also conducted tests on high frequency surgical equipment and accessories for endoscopes per IEC 60601-2-18: Edition 3.0 2009-08 and AAMI/ANSI/IEC 60601-2-2:2009.

Finally, risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971 Second edition 2007-03-01. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The following standards have been applied to the Single Use Electrosurgical Snare SD-400:

Standard #	Standard Title	Related Documents
ISO 11135 Second edition 2014	Sterilization of Health-Care Products Ethylene Oxide - Requirements for The Development, Validation and Routine Control of A Sterilization Process For Medical Devices	Section14
ISO 10993-7 Second edition 2008-10-15	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009)]	Section14
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Section14
AAMI/ANSI/ISO 11607-1:2006/(R)2010	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]	Section14

Standard #	Standard Title	Related Documents
AAMI/ANSI/ISO 11607-2:2006/(R)2010	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)]	Section14
ISO 10993-1 Fourth edition 2009-10-15	Biological evaluation of medical devices – Part1 Evaluation and testing within a risk management process [including: technical corrigendum 1 (2010)]. (Biocompatibility)	Section15
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices – Part5 Tests for in vitro cytotoxicity	Section15
ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices – Part10 Tests for irritation and skin sensitization	Section15
ISO 10993-11 Second Edition 2006-08-15	Biological evaluation of medical devices - Part 11 Tests for systemic toxicity	Section15
AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, 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).	Section17
IEC 60601-1-2 Edition 3: 2007-03	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility –requirements and tests	Section17
AAMI / ANSI IEC 60601-2-2:2009	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories.	Section17
IEC 60601-2-18 Edition 3.0 2009-08,	Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment.	Section17
ISO 14971 Second edition 2007-03-01	Medical devices-Application of risk management to medical devices	Section21

VIII. Conclusion

Compared to the predicate device, the proposed design modifications to the Single Use Electrosurgical Snare SD-400 were verified and validated and did not raise any new issues with safety and effectiveness. Therefore, the subject device is substantially equivalent to the cited predicate device.