December 17, 2019

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

Re: K193039
Trade/Device Name: Single Use Balloon Dilator V (with knife)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: KNS, FGE
Dated: October 30, 2019
Received: October 31, 2019

Dear Sheri 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. 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,

Daniel G. Walter, Jr.
Assistant Director
THT3A3: Obesity and Hepatobiliary Devices
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)*

K193039

Device Name
Single Use Balloon Dilator V (with Knife)

Indications for Use *(Describe)*
These instruments have been designed to be used with an Olympus endoscope for papillotomy and for dilating the major papilla to retrieve biliary stones.

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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October 30, 2019

Section 5
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: Sheri L. Musgnung
Olympus Corporation of the America
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

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

5.2 DEVICE IDENTIFICATION

■ Device Name: Single Use Balloon Dilator V (with knife)

■ Model Name:
BD-VC431Q-1240-20
BD-VC431Q-1240-25
BD-VC431Q-1240-30

■ Common Name: Single Use Balloon Dilator (with knife)

■ Regulation Number:
876.4300
876.5010

■ Regulation Name:
Endoscopic electrosurgical unit and accessories.
Biliary catheter and accessories.

■ Regulatory Class: II

■ Product Code KNS
FGE

■ Classification Panel Gastroenterology/Urology

5.3 PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
Single Use Balloon Dilator V (with knife)	OLYMPUS MEDICAL SYSTEMS CORP.	K150142

5.4 DEVICE DESCRIPTION

■ **General Description of the subject device**

The subject device consists of the balloon and the papillotomy knife for endoscopic sphincterotomy.

The only difference from the predicate device which has been cleared under K150142 is the additional balloon diameter offerings

The intended use of the subject device is identical to the predicate device.

■ **Principle of Operation**

There are no differences in composition and basic principle compared with the predicate.

The subject device used in combination with compatible Olympus endoscopes, A-Cord (power cable), electrosurgical unit and compatible inflation device and the subject device is inserted endoscopically into the body cavity, and a tissue is cut by applying a high frequency current while the cutting wire is tightened.

In addition, an inflation device is attached to a balloon port, and the inflation fluid is injected by utilizing an inflation device to dilate the papilla.

The insertion portion of this product has a V-marking, and the relative insertion length of this product into the endoscope can be confirmed by the positional relationship between the V-marking and the biopsy valve of the endoscope.

The Hook provided on the handle is for attaching the subject device to an endoscope or an inflation device, which assists manipulation of the subject device.

5.5 INDICATIONS FOR USE

These instruments have been designed to be used with an Olympus endoscope for papillotomy and for dilating the major papilla to retrieve biliary stones.

5.6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The Single Use Balloon Dilator V (with knife) has the same technological characteristics and design as the predicate device except for the following new feature:

- smaller balloon diameters

All other technological characteristics of both the subject and predicate device are identical.

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

Comparison Table

Item	Subject Device	Predicate Device
	BD-VC431Q-1240-20/25/30	BD-VC431Q-1840-20/25/30
Distal tip diameter (mm)	ø1.5 mm	ø1.5 mm
Tip length (mm)	7 mm	7 mm
Knife length (mm)	20 mm / 25 mm / 30 mm	20 mm / 25 mm / 30 mm
Maximum insertion portion diameter (mm) (before inflating the balloon)	ø 3.65 mm	ø 3.65 mm
Working length (mm)	1950 mm	1950 mm
Balloon diameter (mm (Fr)) / Pressure (bar (atm))	ø 8 mm(24Fr) / 0.5bar(0.5atm) ø 10mm(30Fr) / 2bar(2atm) ø 12mm(36Fr) / 3.5bar(3.5atm)	ø 12 mm(36Fr) / 0.5bar(0.5atm) ø 15mm(45Fr) / 2bar(2atm) ø 18mm(54Fr) / 3.5bar(3.5atm)
Balloon length (mm)	40mm	40mm
Maximum pressure (bar (atm))	3.5 bar (3.5 atm)	3.5 bar (3.5 atm)
Shape of the distal end	Pre-curved	Pre-curved
Knife wire diameter (mm)	ø 0.2 mm	ø 0.2 mm
Coated portion	Provided	Provided
Lumen type	4-Lumen with C-channel	4-Lumen with C-channel

5.7 PERFORMANCE DATA

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

1) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Single Use Balloon Dilator V (with knife). The system complies with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2014 standards for EMC.

2) Sterilization/Shelf-life testing

Sterilization/shelf-life testing for the Single Use Balloon Dilator V (with knife) was 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 Single Use Balloon Dilator V (with knife) was conducted in accordance with ASTM F1980-16(2016), the standard guide for accelerated aging of sterile barrier systems for medical devices. The three years real-time aging test will be performed to demonstrate longer stability and support the results of the accelerated aging test.

3) Biocompatibility testing

Biocompatibility testing for the Single Use Balloon Dilator V (with knife) were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1:2009, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

Contact classification;
The Single Use Balloon Dilator V (with knife) is considered a surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (i.e. contact is up to 24 hours).

4) Performance testing - Bench

Bench testing for the Single Use Balloon Dilator V (with knife) as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

Dimensional verification
Endoscopic compatibility

Knife operation
Papillotomy resistance
Tensile strength
Balloon deflation time
Balloon burst strength
Balloon fatigue
Package integrity

5) Risk analysis

Risk analysis for the Single Use Balloon Dilator V (with knife) was 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 device, the Single Use Balloon Dilator V (with knife) raise no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.