November 27, 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: K170811
Trade/Device Name: Single Use Retrieval Nitinol Basket V
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and Accessories
Regulatory Class: II
Product Code: LQR, OCZ
Dated: October 16, 2017
Received: October 17, 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,

Joyce M. Whang -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)*
K170811

Device Name
Single Use Retrieval Nitinol Basket V

Indications for Use *(Describe)*
This instrument has been designed to be used with Olympus endoscopes to retrieve stones from the biliary 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)

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.

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."

510(k) SUMMARY

Single Use Retrieval Nitinol Basket V

November 27, 2017

5.1 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

5.2 Device Identification

■ Device Trade Name:	Single Use Retrieval Nitinol Basket V
■ Common Name:	Retrieval Basket
■ Regulation Number:	876.5010
■ Regulation Name:	Biliary Catheter and Accessories
■ Regulatory Class:	II
■ Classification Panel:	Gastroenterology and urology
■ Product Code:	LQR, OCZ

5.3 Predicate Device Information

Device Trade Name	Common Name	Applicant	510(k) number
TRAPEZOID RX LITHOTRIPTER COMPATIBLE BASKET, MODELS 1086, 1087, 1088	Retrieval Basket / Lithotripsy Basket	BOSTON SCIENTIFIC CORP.	K040447
Olympus Basket Graspers	Grasping forceps	OLYMPUS AMERICA INC.	K955063

5.4 Device Description

The subject device is designed to be used with Olympus endoscopes to retrieve stones from the biliary tract.

This product consists of the operation portion (Handle) and insertion portion.
The insertion portion consists of distal end portion and sheath portion.
The distal end portion contains a basket. The Basket is connected to the Control grip of the operating portion through the insertion portion. Activating the Control grip allows the basket to open or close.

The insertion portion and the distal end portion of the subject device are inserted into the biliary tract through the endoscope. The Basket opens to retrieve the stones from the biliary tract.

5.5 Indications for Use

This instrument has been designed to be used with Olympus endoscopes to retrieve stones from the biliary tract.

5.6 Comparison of Technological Characteristics

Compared to the predicate devices, the proposed subject device; Single Use Retrieval Nitinol Basket V, has similar technological characteristics. There is no significant difference that affects the safety or effectiveness of the subject device.

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.

•Biocompatibility testing
Biocompatibility testing is 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"” including cytotoxicity, sensitization, and irritation testing.

•Performance testing including sterilization validation, shelf life, and mechanical performance/bench testing was conducted to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

Sterilization validation

Sterilization validation was carried out with Methods Half-cycle approach in accordance with ISO 11135:2014.

Shelf life testing

Shelf life testing was conducted based on an accelerated aging test in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. Three years real-time aging test will be performed to demonstrate longer stability and support the results of the accelerated aging test.

Mechanical performance testing

Mechanical performance testing was conducted on the following items to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

1, Insertion / withdrawal
2, Open/Close basket
3, Dimensions of the basket
4, Attachment / Detachment of hook

5, Injecting fluid
6, Visual inspection of package
7, Peel strength of the package
8, Endurance to splitting of the package
9, Integrity of the package
10, Maximum diameter of catheter
11, Working length of the catheter
12, Position of V marking
13, Strength of junction

·The following standards have been applied to the Single Use Retrieval Nitinol Basket V.

Standard number	Standard Title
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)]
AAMI ANSI ISO 10993-5:2009/(R)2014	Biological Evaluation Of Medical Devices – Part5: Tests For In Vitro Cytotoxicity
ISO 10993-10 Third Edition: 2010-08-01	Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
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.
ASTM F1980-16	Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices
ISO 14971 Second Edition: 2007-03-01	Medical Devices - Application Of Risk Management To Medical Devices

5.8 Conclusion

When compared to the predicate device, the Single Use Retrieval Nitinol Basket V 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.