September 1, 2020

Olympus Medical Systems Corp.
℅ Lisa Boyle
Regulatory Affairs Specialist II
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, Pennsylvania 18034-0610

Re: K201920
Trade/Device Name: Endoscope Reprocessor OER-Elite
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FEB
Dated: July 6, 2020
Received: July 10, 2020

Dear Lisa Boyle:

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,

CAPT Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K201920

Device Name
ENDOSCOPE REPROCESSOR OER-Elite

Indications for Use *(Describe)*

The OER-Elite is intended for use in cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes, their accessories, and endoscope reprocessor accessories. Safe use requires detergent and an FDA-cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Elite and Olympus flexible endoscopes, their accessories, and endoscope reprocessor accessories. Use of a detergent or high-level disinfectant/sterilant that has not been validated by Olympus may be ineffective and can damage the OER-Elite components and the endoscopes being reprocessed. Endoscopes must be cleaned by the user prior to reprocessing; however, use of the OER-Elite enables the user to perform modified manual cleaning of some endoscopes prior to automated cleaning and high-level disinfection in the OER-Elite.

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.

Date Prepared: September 1, 2020

K201920
510(k) Summary

1. GENERAL INFORMATION

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

■ Contact Person: Lisa Boyle
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■ Manufacturing site: Aizu Olympus Co., Ltd.,
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Fukushima 965-8520, Japan

2. DEVICE IDENTIFICATION

■ Device Name: ENDOSCOPE REPROCESSOR OER-Elite

■ Model Name: OER-Elite

■ Common Name: Endoscope washer/disinfector

■ Regulation Number: 876.1500

■ Regulation Name: Endoscope and accessories

■ Regulatory Class: II

■ Product Code: FEB - Accessories, Cleaning, For Endoscope

■ Classification Panel: Gastroenterology/Urology

3. PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
ENDOSCOPE REPROCESSOR OER-Elite	OLYMPUS MEDICAL SYSTEMS CORP.	K190969

4. DEVICE DESCRIPTION

■ **General Description of the subject device**

The OER-Elite Endoscope Reprocessor is an automated endoscope reprocessor intended for high-level disinfection of Olympus flexible endoscopes, their accessories, and endoscope reprocessor accessories, utilizing both a detergent and FDA cleared high-level disinfectant validated by Olympus to be efficacious and compatible with the materials of the OER-Pro and Olympus flexible endoscopes, their accessories, and endoscope reprocessor accessories.

The OER-Elite originally featured an “extra disinfection process” which can provide an extra three-minute process for delivering fluid to both the forceps elevator area and elevator wire channel when reprocessing endoscopes with a forceps elevator.
The software of the OER-Elite was changed to apply the “extra disinfection process” to the ultrasound endoscope with balloon channel in addition to the endoscopes with a forceps elevator.

The proposed OER-Elite differs from the predicate OER-Elite in the following minor modifications:

a) Add “Extra disinfection process” to ultrasound endoscope with balloon channel.
b) Optimize the threshold values of existing error codes.
c) Replace the electronic cooling fan due to discontinuing of the product.
d) Change the material used for fluid pathways.

■ **Principle of Operation**

The principle of operation has not been changed from that of the predicate OER-Elite.
The OER-Elite is a one-basin automatic endoscope reprocessor that performs leak testing, cleaning, disinfection, rinsing, and an alcohol flush to render a high-level disinfected endoscope, their accessories, and endoscope reprocessor accessories.

The OER-Elite utilizes an immersion method for cleaning, disinfecting, and rinsing of endoscope and accessory external surfaces, and connectors for endoscope channel cleaning, disinfecting, and rinsing. Two endoscopes, with several exceptions, can be reprocessed simultaneously in the basin during one reprocessing cycle. The OER-Elite's cleaning cycle includes ultrasonic cleaning, which helps remove debris and dirt from endoscope surfaces.

The OER-Elite is capable of fully automated detergent/disinfectant solution dispensing and alcohol/air drying of endoscope channels. The 0.2-micron air/water filters are bacteria retentive and produce suitable rinse water and air for reprocessing. Built-in sensors detect fluid levels, fluid temperature, air/fluid pressure, fluid flow, and the operating states of the components within the OER-Elite.

The OER-Elite is also equipped with a RFID (Radio-Frequency Identification) function. With a built-in antenna, the OER-Elite is capable of reading user and scope ID data from the proprietary ID tag/chip. The scope/user ID information and each reprocessing result can be printed out with a built-in printer, displayed on a touch screen, or exported to a portable memory.

The OER-Elite is capable of using a concentrated disinfectant (e.g., Acecide-C) sealed in dedicated cassette bottles. The concentrated disinfectant is automatically diluted by filtered water until it reaches a specified quantity in the device.

5. INDICATIONS FOR USE

The OER-Elite is intended for use in cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes, their accessories, and endoscope reprocessor accessories. Safe use requires detergent and an FDA-cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Elite and Olympus flexible endoscopes, their accessories, and endoscope reprocessor accessories. Use of a detergent or high-level disinfectant/sterilant that has not been validated by Olympus may be ineffective and can damage the OER-Elite components and the endoscopes being reprocessed. Endoscopes must be cleaned by the user prior to reprocessing; however, use of the OER-Elite enables the user to perform modified manual cleaning of some endoscopes prior to automated cleaning and high-level disinfection in the OER-Elite.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The OER-Elite has the same technological characteristics and design as the predicate device except for the subject of the "extra disinfection process" to the ultrasound endoscope with balloon channel. All other technological characteristics of both the subject and predicate device are identical.

The comparison to the Predicate Device was summarized in the Table shown below.

Features	Subject Device: OER-Elite	Predicate Device: OER-Elite (K190969)	Comment on difference
Intended Use	The OER-Elite is intended for use in cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes, their accessories, and endoscope reprocessor accessories. Safe use requires detergent and an FDA-cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Elite and Olympus flexible endoscopes, their accessories, and endoscope reprocessor accessories. Use of a detergent or high-level disinfectant/sterilant that has not been validated by Olympus may be ineffective and can damage the OER-Elite components and the endoscopes being reprocessed. Endoscopes must be cleaned by the user prior to reprocessing; however, use of the OER-Elite enables the user to perform modified manual cleaning of some endoscopes prior to automated cleaning and high-level disinfection in the OER-Elite.	The OER-Elite is intended for use in cleaning and high-level disinfection of heat sensitive Olympus flexible endoscopes, their accessories, and endoscope reprocessor accessories. Safe use requires detergent and an FDA-cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Elite and Olympus flexible endoscopes, their accessories, and endoscope reprocessor accessories. Use of a detergent or high-level disinfectant/sterilant that has not been validated by Olympus may be ineffective and can damage the OER-Elite components and the endoscopes being reprocessed. Endoscopes must be cleaned by the user prior to reprocessing; however, use of the OER-Elite enables the user to perform modified manual cleaning of some endoscopes prior to automated cleaning and high-level disinfection in the OER-Elite.	Same
Disinfectant	Olympus validated , FDA cleared High-Level Disinfectant (Acecide-C);	Olympus validated , FDA cleared High-Level Disinfectant (Acecide-C);	Same
Detergent	Olympus validated Detergent (EndoQuick)	Olympus validated Detergent (EndoQuick)	Same

Features	Subject Device: OER-Elite	Predicate Device: OER-Elite (K190969)	Comment on difference
Wash/HLD Methods	Cleaning method: - Exterior surfaces Ultrasonic cleaning, turbulent bath Channel interiors Fluid flushing - Valves Ultrasonic cleaning, fluid flushing Disinfection method: - Exterior surfaces Disinfectant solution immersion Channel interiors Disinfectant solution flushing and filling - Valves Disinfectant solution immersion	Cleaning method: - Exterior surfaces Ultrasonic cleaning, turbulent bath Channel interiors Fluid flushing - Valves Ultrasonic cleaning, fluid flushing Disinfection method: - Exterior surfaces Disinfectant solution immersion Channel interiors Disinfectant solution flushing and filling - Valves Disinfectant solution immersion	Same
Independent sub functions	Functions: - Heat LCG - Mix LCG - Rinse - Air Purge - Water Line Disinfection - Self-Disinfection & Water Sampling - Detergent Line Disinfection - Alcohol Line Disinfection - Manual Leak Test - Auto Leak Test - ALT Self-Check - Alcohol Flush - Leaking scope decontamination - Heat LCG Timer Replacement of Consumable Items: - Drain LCG - Load LCG - Replace Detergent - Replace Water Filter - Replace Air Filter Replace Gas Filter on the lid/tank	Functions: - Heat LCG - Mix LCG - Rinse - Air Purge - Water Line Disinfection - Self-Disinfection & Water Sampling - Detergent Line Disinfection - Alcohol Line Disinfection - Manual Leak Test - Auto Leak Test - ALT Self-Check - Alcohol Flush - Leaking scope decontamination - Heat LCG Timer Replacement of Consumable Items: - Drain LCG - Load LCG - Replace Detergent - Replace Water Filter - Replace Air Filter - Replace Gas Filter on the lid/tank	Same
Leak test method	Manual leak testing or Auto leak testing	Manual leak testing or Auto leak testing	Same
Channel monitoring function	Available	Available	Same
User Interface	Graphical User Interface (GUI) and manual control buttons	Graphical User Interface (GUI) and manual control buttons	Same

Features	Subject Device: OER-Elite	Predicate Device: OER-Elite (K190969)	Comment on difference
Extra Disinfection Process	Applied to endoscope models with forceps elevator **and/or balloon channel**	Applied to endoscope models with forceps elevator only.	Endoscope models with balloon channel was added to the subject of the extra disinfection process

7. NON-CLINICAL PERFORMANCE TESTING

Performance testing of the OER-Elite was performed to evaluate the modified device and the results are summarized as follows.

1) **Process Parameter Test**
   Process parameter testing was conducted on the OER-Elite in accordance with recommendations in the FDA Guidance: "FDA guidance "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities" to demonstrate that the machine achieves and maintains the specified physical process parameters, including detection of the defined fault conditions and execution of automatic response/processing following fault detection.

2) **Software verification and validation testing**
   Software verification and validation testing for the OER-Elite was conducted and documentations were provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

3) **Electrical Safety**
   A Design/Specification review of the OER-Elite cooling fan was conducted to demonstrate the new cooling fan does not deviate from the technical specifications of the previous cooling fan which was previously evaluated in the electrical safety testing in accordance with IEC 61010-1:2010 and IEC 61010-2-040:2015.

4) **Durability**
   The components with new fluid pathway materials of the OER-Elite were exposed to the reprocessing chemicals. No functional degradation was observed.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, non-clinical performance testing and technological comparison to the predicate device, the OER-Elite is as safe, as effective, and performs as well or better than the legally marketed predicate device (K190969).