July 9, 2019

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

Re: K190969
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: April 10, 2019
Received: April 12, 2019

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. 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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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)*
K190969

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.

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510(k) Premarket Notification
ENDOSCOPE REPROCESSOR OER-Elite

K190969 510(k) Summary

Date Prepared: April 10, 2019

❑ Applicant Information

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

- Official Correspondent: Daphney Germain-Kolawole
  Olympus Corporation of the Americas
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610
  Phone: 484-896-5691
  Fax: 484-896-7128
  Email: daphney.germain-kolawole@olympus.com

- Manufacturer: AIZU OLYMPUS CO., LTD.
  500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
  Aizuwakamatsu-shi, Fukushima, Japan 965-8520
  Establishment Registration No: 9610595

❑ Device Identification

- Device Trade Name: ENDOSCOPE REPROCESSOR OER-Elite
- Common Name: Endoscope washer/disinfector
- Class: II
- Regulation Number/Name: 876.1500 Endoscope and accessories
- Product Code: FEB - Accessories, Cleaning, For Endoscope
- Classification Panel: Gastroenterology/Urology
- Performance Standard: None established under Section 514 of FD&C Act.

❑ Predicate Device (PD)

- Device Trade Name: ENDOSCOPE REPROCESSOR OER-Pro
- 510(k) Number: K103264
- Manufacturer: AIZU OLYMPUS CO., LTD.

Device Description

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 is a one-basin automatic endoscope reprocessor that performs leak test, cleaning, disinfection, rinse, and 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.

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.

- **Technical Characteristics**

Features	Subject: K190969 OER-Elite	Predicate: K103264 OER-Pro	Comment on the 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-Pro Endoscope Reprocessor is intended to clean and high-level disinfect heat sensitive Olympus flexible endoscopes and their accessories. Use of the OER-Pro requires both a detergent and an FDA-cleared high-level disinfectant/sterilant that Olympus has validated to be efficacious and compatible with the materials of the OER-Pro and Olympus flexible endoscopes and their 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-Pro components and the endoscopes being reprocessed. Endoscopes must be subject to cleaning by the user prior to reprocessing; however, use of the OER-Pro enables the user to perform modified manual cleaning of the endoscope prior to automated cleaning and high-level disinfection in the OER-Pro.	The underlined expression is modified. However, the substantive content remains the same.
Disinfectant	Same as the predicate device except that the Aldahol is not compatible at this time.	Olympus validated , FDA cleared High-Level Disinfectant; Ready-to-use-disinfectant(Aldahol) Concentrated disinfectant (Acecide-C)	Currently, Aldahol is not compatible with the OER-Elite.
Detergent	Same as the predicate device.	Olympus validated Detergent (EndoQuick)	None

Features	Subject: K190969 OER-Elite	Predicate: K103264 OER-Pro	Comment on the Difference
Wash/HLD Methods	Same as the predicate device	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	None

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Features	Subject: K190969 OER-Elite	Predicate: K103264 OER-Pro	Comment on the Difference
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	- Heat LCG - Drain LCG - Load LCG - Water Line Disinfection - Leak Test (Manual) - Alcohol Flush - Air Purge - Rinse	The OER-Elite provides a few new functions as independent sub functions. Process parameter tests and risk analysis were conducted to validate the modifications. As a result, these modifications do not affect the safety and effectiveness of the subject device.
Leak test method	Manual leak testing or Auto leak testing	Manual leak testing	Auto leak testing is added. Process parameter tests and risk analysis were conducted to validate the modification. As a result, this modification does not affect the safety and effectiveness of the subject device.

Features	Subject: K190969 OER-Elite	Predicate: K103264 OER-Pro	Comment on the Difference
Channel monitoring function	Available	Not available	Channel monitoring function is added. Process parameter tests and risk management were conducted to validate the modification. As a result, this modification does not affect the safety and effectiveness of the subject device.
User Interface	Graphical User Interface (GUI) and manual control buttons	Main and sub control panel	Graphical User Interface (GUI) is added. Software validation testing, Human Factors testing, and risk analysis were conducted to validate the modification. As a result, this modification does not affect the safety and effectiveness of the subject device.

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- **Summary of Non-Clinical Testing**

The OER-Elite has been tested following the requirements in the following FDA guidance documents.

- "Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities", issued in August 1993
- "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff", published on August 13, 2013
- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 11, 2005
- "Applying Human Factors and Usability Engineering to Medical Devices", issued on February 3, 2016
- "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", issued on March 17, 2015,

Test reports provided in this premarket notification include:

Process Parameter Test
The OER-Elite was tested to demonstrate that the device performs as intended. The test results showed that the OER-Elite achieves and maintains the specified physical process parameters, including detection of the defined fault conditions and execution of automatic response/processing following fault detection.

Validation Testing - Cleaning
The OER-Elite was tested to evaluate its ability to clean endoscopes in both simulated and in-use conditions. The test results demonstrate that the OER-Elite effectively reduced protein and hemoglobin levels in all sample sites.

Validation Testing – High-Level Disinfection
The OER-Elite was tested to evaluate its ability to high-level disinfect endoscopes and valves in both simulated and in-use conditions. The simulated-use testing demonstrated a 6 Log_{10} reduction of M.terrae at all inoculated sites was achieved after reprocessing in the OER-Elite's disinfection cycle. In-use testing demonstrated no viable microorganisms were recovered from endoscopes and valves following reprocessing in the OER-Elite.

Validation Testing – Full Cycle
The OER-Elite was tested to evaluate its effectiveness for full-cycle reprocessing including both cleaning and disinfection under simulated-use conditions. The simulated-use testing demonstrated that the OER-Elite effectively cleaned and achieved high-level disinfection for Olympus endoscopes and valves.

Simulated-Use Testing – Self-Disinfection
Simulated-use testing was performed to validate self-disinfection of the OER-Elite. Testing demonstrated that a greater than 6 log reduction in M. terrae was achieved for all sample locations after completion of routine reprocessing of endoscopes within the OER-Elite.

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Simulated-Use Testing – Water Line Disinfection
The simulated-use testing was performed to validate disinfection of the OER-Elite water line piping which does not contact high-level disinfectant during routine reprocessing. The test result showed that a greater than 6 log reduction in M. terrae was achieved for all sample locations after completion of the water line disinfection procedure.

Toxicological Evaluation of Residues
The safety of residual chemicals remaining on endoscopes after reprocessing in the OER-Elite was evaluated. The test results showed that the OER-Elite reprocessing cycle removes detergent and disinfectant residues to non-toxic levels. The testing was conducted in accordance with ISO 10993-5:2009.

Human Factors Testing
Human Factors studies were conducted with the OER-Elite. The study participants received training that was consistent with the commercial product. Usability evaluations were performed that included critical tasks and results of the study demonstrated that the potential benefits of the device outweighed the risks.

Risk analysis
Risk analysis for the OER-Elite 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.

Software verification and validation testing
Software verification and validation testing for the OER-Elite were conducted and documentation was 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".

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the OER-Elite. The system complies with the IEC 61010-1:2010 and IEC 61010-2-040:2015 standards for safety and the IEC 61326-1:2012 standards for EMC.

Federal Communication Commission (FCC) Rules and RFID function
The OER-Elite utilizes a radio frequency identification (RFID) system to identify both endoscope (model and serial number) and user identification for the development of printed reports following endoscope reprocessing in the OER-Elite. To perform these functions, the OER-Elite emits radio frequency (RF) output at the frequency of 13.56MHz. As the OER-Elite is considered to be an intentional radiator prescribed under Federal Communications Commission (FCC) 47 CFR Part 15 – Radio Frequency Devices, Subpart C – Intentional Radiators, it has also been evaluated to verify compliance with this regulation and FDA guidance "Radio-Frequency Wireless Technology in Medical Devices".

- **Conclusion**

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K103264).