September 26, 2025

Olympus Medical Systems Corporation
% Brenda Geary
Senior Manager, Regulatory Affairs
Olympus Corporations of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K251986
Trade/Device Name: Auxiliary Water Tube MAJ-855
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCX
Dated: June 27, 2025
Received: June 27, 2025

Dear Brenda Geary:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SIVAKAMI VENKATACHALAM -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251986

Please provide the device trade name(s).

AUXILIARY WATER TUBE MAJ-855

Please provide your Indications for Use below.

The AUXILIARY WATER TUBE MAJ-855 is intended to be used to provide sterile water, detergent solution, disinfectant solution, water, and alcohol for irrigation through the auxiliary water channel of compatible endoscopes.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2025-06-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Olympus Medical Systems Corporation
Applicant Address	2951 Ishikawa-cho Hachioji-shi Tokyo 192-8507 Japan
Applicant Contact Telephone	+8 142-642-269
Applicant Contact	Mr. Shinichiro Kawachi
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Correspondent Name	Olympus Corporation of the Americas
Correspondent Address	800 West Park Drive Westborough MA 01581 United States
Correspondent Contact Telephone	508-683-9561
Correspondent Contact	Ms. Brenda Geary
Correspondent Contact Email	Brenda.Geary@olympus.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	AUXILIARY WATER TUBE MAJ-855
Common Name	Endoscope and accessories
Classification Name	Endoscopic Irrigation/Suction System
Regulation Number	876.1500
Product Code(s)	OCX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220395	Endogator Endoscopy Irrigation Tubing & Accessories	FEQ
K232997	EVIS EXERA III GIF-1TH190 (Auxiliary Water Tube MAJ-855)	FET

Device Description Summary

21 CFR 807.92(a)(4)

The Auxiliary Water Tube MAJ-855 is used in endoscopic procedures to flush sterile water through the auxiliary water channel to wash the endoscopic field of view. Sterile water for washing the mucosa can be provided either manually by use of a syringe or automatically via a flushing pump. The MAJ-855 can be used both during an endoscopic procedure and reprocessing (i.e. pre-cleaning, manual cleaning and manual disinfection).

The Auxiliary Water Tube MAJ-855 is a reusable device, provided to the user in a non-sterile condition and must be reprocessed prior to first use and following each use (i.e., after each patient exam).

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The AUXILIARY WATER TUBE MAJ-855 is intended to be used to provide sterile water, detergent solution, disinfectant solution, water, and alcohol for irrigation through the auxiliary water channel of compatible endoscopes.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Auxiliary Water Tube MAJ-855 is connected to an endoscope with an auxiliary water channel for both irrigation during a procedure and reprocessing. The indications for use of the subject device, 'to provide sterile water, detergent solution, disinfectant solution, water, and alcohol for irrigation through the auxiliary water channel of compatible endoscopes' are a combination of Medivators Inc. Endogator Endoscopy Irrigation Tubing & Single Use Auxiliary Water Jet Connector which is used for irrigation during a procedure and the intended use of the Auxiliary Water Tube MAJ-855 which was cleared as an accessory to the Olympus EVIS EXERA III GIF-1TH190 under K232997 to be used to provide irrigation during a procedure and for reprocessing.

Technological Comparison 21 CFR 807.92(a)(6)

When used during a procedure, the subject device and predicate Endogator Endoscopy Irrigation Tubing & Single Use Auxiliary Water Jet Connector have the same principles of operation in that they are accessory tubing that achieve its intended purpose by directing flow of sterile water from a flushing pump to the auxiliary water channel of an endoscope. Both devices have a built-in backflow prevention valve to reduce the risk of cross contamination. The devices differ in the setup and use of compatible accessories to achieve the intended purpose as well as reusability, as the subject device is reusable multi-patient, whereas the predicate is 24-hour multi-patient. Differences in setup and compatible accessories do not raise new questions on safety or effectiveness, as both devices, when setup for the procedure, are intended to serve the same purpose and testing demonstrates equivalent performance. While there are differences in limits of use between the subject and predicate device, the Auxiliary Water Tube MAJ-855 previously cleared as an accessory to the Olympus EVIS EXERA III GIF-1TH190 is a reusable device, and durability testing has been conducted to demonstrate this difference raises no new questions on safety or effectiveness.

The subject device is used for reprocessing like the predicate Auxiliary Water Tube MAJ-855 which was cleared as an accessory to the Olympus EVIS EXERA III GIF-1TH190. The subject device is identical to the accessory device previously cleared.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing was determined based on the device risk assessment, applicable FDA Guidance documents and industry recognized standards. Performance bench testing as listed below were conducted to demonstrate the device is safe and effective for its intended use and is substantially equivalent to the predicate device. Bench tests were performed on reprocessed devices. The test results have demonstrated substantial equivalence of the subject device to the predicate device.

- Functional Testing
- Water Supply rate
- Durability Testing
- Backflow Prevention Testing

Product performance testing of the subject device was conducted, and the device passed all the pre-defined acceptance criteria for each test item demonstrating that design verification has been met. The side-by-side testing for substantial equivalence has demonstrated that the subject device and the predicate device are substantially equivalent and do not raise any new issues of safety or effectiveness.