October 7, 2024

Olympus Medical Systems Corporation
% Teffany Hutto
Regulatory Affairs Program Manager
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K242357
Trade/Device Name: Water Container (MAJ-901); Water Container (MAJ-902)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCX
Dated: August 8, 2024
Received: August 8, 2024

Dear Teffany Hutto:

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,

Shanil P. Haugen -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242357

Device Name

Water Container (MAJ-901)
Water Container (MAJ-902)

Indications for Use *(Describe)*

The water container MAJ-901 has been designed to be used with endoscopes to allow gas insufflation and water feeding from the endoscope.

Do not use this instrument for any purpose other than its intended use.

The water container MAJ-902 has been designed to be used with endoscopes to allow gas insufflation and water feeding from the endoscope.

Do not use this instrument for any purpose other than its intended use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #:

510(k) Summary

Prepared on: 2024-08-12

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	+81 42-642-269
Applicant Contact	Mr. Shinichiro Kawachi
Applicant Contact Email	Shinichiro.Kawachi@olympus.com
Correspondent Name	Olympus Corporation of the Americas
Correspondent Address	800 West Park Drive Westborough MA 01581 United States
Correspondent Contact Telephone	5125086550
Correspondent Contact	Mrs. Teffany Hutto
Correspondent Contact Email	teffany.hutto@olympus.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Water Container (MAJ-901); Water Container (MAJ-902)
Common Name	Endoscopes and Accessories
Classification Name	Endoscope and accessories
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
K093665	Endo SmartCap [Model: 100145]	FAJ

Device Description Summary

21 CFR 807.92(a)(4)

The MAJ- 901 and MAJ-902 have been designed to be used with Olympus light sources and endoscopes to allow gas insufflation and water feeding from the endoscope.

MAJ-901 and MAJ-902 are both comprised of a Lid, Container, O-ring, and Container Protector. Other than Lid, the devices are the same.

MAJ-902 also includes a "gas tube connector" in the lid for carbon dioxide gas delivery. Additionally, MAJ-902 includes a Caution tag that the MAJ-901 does not.

The MAJ-901 and MAJ-902 are reusable, multi-patient devices.

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

The water container MAJ-901 has been designed to be used with endoscopes to allow gas insufflation and water feeding from the endoscope.

Do not use this instrument for any purpose other than its intended use.

The water container MAJ-902 has been designed to be used with endoscopes to allow gas insufflation and water feeding from the endoscope.

Do not use this instrument for any purpose other than its intended use.

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

The Water Containers MAJ-901 and MAJ-902 have been designed to be used with Olympus light sources and endoscopes to allow gas insufflation and water feeding from the endoscope. The Indications for Use statement for the predicate Endo SmartCap is not identical to the predicate device as it is also intended to provide air; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for insufflation and water feeding to the endoscope.

Technological Comparison 21 CFR 807.92(a)(6)

• Principle of Operation
Both subject devices and predicate device have the same principles of operation, providing pressurized gas or air into the container/ bottle by the endoscope's processor/light source and the water, air (MAJ-901) or gas (MAJ-902) is fed into the endoscope through the tube.

• Both Subject Devices and Predicate Device are compatible with Olympus endoscopes

• Patient Contact Duration
Both subject devices and predicate device have indirect contact with the patient.

Differences
• The Subject Devices are reusable, and the Predicate Device is single use.
• The Subject Devices and the Predicate Device utilize different materials.

The subject devices have undergone comparative performance testing, non-clinical bench testing, biocompatibility testing, and reprocessing validations to demonstrate the differences do not raise new questions of safety or effectiveness, and therefore, is substantially equivalent to the predicate device.

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

Performance testing - Bench
Bench testing as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

• Flow Rate
• Durability (GA)
• Durability (AC)
• Biocompatibility
• Reprocessing
• Human Factors

All testing demonstrated that the subject devices met design specifications and performed as intended.

No clinical testing was submitted in this 510(k) application.