July 16, 2025

Olympus Medical Systems Corporation
% Susan Lewandowski
Program Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K250949
Trade/Device Name: Suction Valve (MAJ-1443); Air/Water Valve (MAJ-1444)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC
Dated: March 28, 2025
Received: March 28, 2025

Dear Susan Lewandowski:

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.	K250949
Please provide the device trade name(s).	

Suction Valve (MAJ-1443);
Air/Water Valve (MAJ-1444)

Please provide your Indications for Use below.

The AIR/WATER VALVE MAJ-1444 and SUCTION VALVE MAJ-1443 have been designed for use with an Olympus ultrasound endoscope for the gastrointestinal (GI) tract, as follows.

Air/Water Valve (MAJ-1444)
- To feed air to remove any fluids or debris adhering to the objective lens.
- To feed water for lens washing.
- To fill the balloon with sterile water.

Suction Valve (MAJ-1443)
- To remove any fluids, debris, or air from the patient.
- To remove the water from the balloon.

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) Summary

1. General Information

Date Prepared: March 28, 2025

510(K) submitter: Olympus Medical Systems Corporation
2951 Ishikawa-cho, Hachioji-shi, Tokyo Japan 192-8507

Contact: Osamu Tamada
Product RA Lead GI Endoscope, OMSC

Correspondent: Olympus Surgical Technologies of America
800 West Park Drive, Westborough, MA 01581

Primary Contact: Susan Lewandowski
Email: susan.lewandowski@olympus.com

2. Device Information

Device Name: Suction Valve MAJ-1443, Air/Water Valve MAJ-1444
Common Name: Endoscope channel accessory
Classification: 876.1500 – Endoscope and accessories
Regulatory Class: II
Product Code: ODC (endoscope channel accessory)
Device Panel: Gastroenterology & Urology

3. Predicate Device Information

BioGuard EUS Air/Water and Suction Valves K202104

4. Device Description

The Suction Valve MAJ-1443 and Air/Water Valve MAJ-1444 have been designed for use with an Olympus ultrasound endoscope for the gastrointestinal (GI) tract. The subject devices are reusable. The subject devices are compatible with Olympus endoscopes GF-UCT180 and GF-UE160-AL5.

The Suction Valve MAJ-1443 is attached to the suction cylinder of a compatible endoscope to remove any fluids, debris, or air from the patient and to remove water from the balloon. Suction Valve MAJ-1443 has no patient-contacting components and is a reusable device.

The Air/Water Valve MAJ-1444 is attached to the air/water cylinder of a compatible endoscope to feed air to remove any fluid or debris adhering to the objective lens, to feed water for lens

washing, and to fill the balloon with sterile water. MAJ-1444 has indirect patient-contacting components and is a reusable device.

The subject device has the same technological characteristics and similar design as the applicable predicate device.

5. Indications for Use

The Suction Valve MAJ-1443 and Air/Water Valve MAJ-1444 have been designed for use with an Olympus ultrasound endoscope for the gastrointestinal (GI) tract, as follows:

Suction Valve MAJ-1443

- To remove any fluids, debris, or air from the patient
- To remove the water from the balloon

Air/Water Valve MAJ-1444

- To feed air to remove any fluid or debris adhering to the objective lens
- To feed water for lens washing
- To fill the balloon with sterile water

6. Predicate Comparison

Description	Subject Device (SD) Suction Valve MAJ-1443 Air/Water Valve MAJ-1444	Predicate Device (PD) BioGuard EUS Air/Water and Suction Valves K202104	Comparison
Product Code	ODC	ODC, FDF	SAME The predicate device additionally has the assigned FDA product code FDF (colonoscope and accessories, flexible/rigid) which the subject device does not have.
Classification	II	II	SAME
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	SAME
Common Name	Endoscope channel accessory	Endoscope channel accessory	SAME
Regulation Name	Endoscope and accessories	Endoscope and accessories	SAME
Review Panel	Gastroenterology and Urology	Gastroenterology and Urology	SAME
Indications for Use	The Suction Valve MAJ-1443 and Air/Water Valve MAJ-1444 have been designed for use with an Olympus ultrasound endoscope for the gastrointestinal (GI) tract, as follows:	The BioGuard EUS Suction Valve is intended to be used to control the suction function of an endoscope during a GI endoscopic procedure.	SAME The SD and PD have the same intended use/indications for use but are phrased differently. The SD indications statement specifically details the

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Suction Valve MAJ-1443 and Air/Water Valve MAJ-1444

Description	Subject Device (SD) Suction Valve MAJ-1443 Air/Water Valve MAJ-1444	Predicate Device (PD) BioGuard EUS Air/Water and Suction Valves K202104	Comparison
	Suction Valve MAJ-1443 • To remove any fluids, debris, or air from the patient • To remove the water from the balloon Air/Water Valve MAJ-1444 • To feed air to remove any fluid or debris adhering to the objective lens • To feed water for lens washing • To fill the balloon with sterile water	The BioGuard EUS Air/Water Valve is intended to be used to control the air/water function of an endoscope during a GI endoscopic procedure.	expected use/function of the valves.
Compatible Endoscopes	Olympus GI ultrasound endoscope (with a balloon channel)	Olympus GI ultrasound endoscope (with a balloon channel)	SAME The PD has been designed to be used with an Olympus GI ultrasound endoscope (with a balloon channel)
Single Use	No	Yes	DIFFERENT Performance testing was conducted to demonstrate that this difference in technology does not impact the safety or effectiveness of the SD.
Function	Suction valve • remove any fluids, debris, or air from the patient. • remove the water from the balloon. Air/water valve • feed air to remove any fluid or debris adhering to the objective lens. • feed water for lens washing. • fill the balloon with sterile water.	Suction valve • remove any fluid or debris adhering to the objective lens. • remove the water from the balloon. Air/water valve • feed air to remove any fluid or debris adhering to the objective lens. • feed water for lens washing. • fill the balloon with sterile water.	SAME
Reprocessing Method	- Manual cleaning - Manual disinfection - Autoclaving	Not applicable as the PD is single use	DIFFERENT Performance testing was conducted to demonstrate

Description	Subject Device (SD) Suction Valve MAJ-1443 Air/Water Valve MAJ-1444	Predicate Device (PD) BioGuard EUS Air/Water and Suction Valves K202104	Comparison
			that this difference in technology does not impact the safety or effectiveness of the SD.
Method of application	Manual actuation	Manual actuation	SAME

7. Non-Clinical/Clinical Tests Summary and Conclusion

Olympus performed bench testing to demonstrate the functionality of the Suction Valve MAJ-1443 and the Air/Water Valve MAJ-1444. Test samples were final, finished devices subjected to the full manufacturing process.

The following performance bench tests were conducted. All test samples passed pre-defined acceptance criteria.

Suction Valve MAJ-1443 - Endoscope compatibility, Suction rate, Balloon suction rate, Leakage, Depression Force, and Composite Durability

Air/Water Valve MAJ-1444 - Endoscope compatibility, Air flow rate, Water flow rate, Balloon water rate, Leakage, Depression Force, Composite Durability, and Microbiological Evaluation of Backflow Prevention

8. Conclusion

Based on the comparison to the predicate device, intended use, technological characteristics, and performance testing, the Suction Valve MAJ-1443 and the Air/Water Valve MAJ-1444 raise no new issues of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, efficacy, and performance.