September 25, 2025

Olympus Medical Systems Corporation
Jillian Connery
Program Manager Regulatory Affairs
2951 Ishikawa-cho
Hachioji-shi, Tokyo 192-8507
Japan

Re: K251997
Trade/Device Name: Single-Use Biopsy Valve (MAJ-1555)
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 Jillian Connery:

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.*

510(k) Number *(if known)*
K251997

Device Name
Single-Use Biopsy Valve (MAJ-1555)

Indications for Use *(Describe)*
The SINGLE USE BIOPSY VALVE MAJ-1555 has been designed to be attached to the instrument channel port of the endoscopes and to provide access for endoscopic device passage and exchange, help maintain insufflation, minimize leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provide access for irrigation.

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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# SINGLE USE Biopsy Valve

## 510(k) SUMMARY

**510(k) Summary: K251997**

## 1. COMPANY INFORMATION

**• Applicant**

OLYMPUS MEDICAL SYSTEMS CORPORATION
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507, Japan
FDA Establishment Registration #: 8010047

**• Official Correspondent**

Jillian Connery
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Email: jillian.connery@olympus.com

**• Manufacturing Site**
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34-3 Hirai, Hinode-machi
NISHITAMA-GUN Tokyo, JP 190-0182
FDA Establishment Registration #; 3003637092
• **Date Prepared:** 3-Sep -2025

## 2. PRODUCT INFORMATION

- Trade Name: Single Use Biopsy Valve MAJ-1555
- Models: MAJ-1555
- Common Name: Biopsy Valve
- Classification Name: Endoscope and accessories
- Product Code: OCX
- Regulation Number: 21 CFR 876.1500
- Regulation Name: Endoscope and accessories
- Device Class: II

## 3. PREDICATE DEVICE

- Trade Name: Seal™ Single Use Biopsy Valve
- Model: SBC-501
- 510(k) Number: K182275

## 4. DEVICE DESCRIPTION

The Olympus Single Use Biopsy Valve MAJ-1555 is a sterile, disposable device designed to attach to the instrument channel port of Olympus endoscopes. It facilitates the passage and exchange of endoscopic devices, helps maintain insufflation, minimizes leakage of biomaterial, and prevents reflux of body fluids. The device consists of a cap and inner rubber made of silicone rubber, and a housing made of polyethylene. A lever mechanism prevents reuse after detachment.

## 5. INDICATIONS FOR USE

The SINGLE USE BIOPSY VALVE MAJ-1555 has been designed to be attached to the instrument channel port of the endoscopes and to provide access for endoscopic device passage and exchange, help maintain insufflation, minimize leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provide access for irrigation.

## 6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The MAJ-1555 is substantially equivalent to the Boston Scientific Seal™ Single Use Biopsy Valve (K182275) in terms of:

- **Intended Use:** Both devices are used to facilitate endoscopic procedures by allowing device passage, maintaining insufflation, and minimizing leakage.
- **Technological Characteristics:** Both are single-use, sterile biopsy valves made of biocompatible materials.
- **Performance:** Both devices meet performance criteria for leakage prevention, device passage, and usability.

Differences such as the inclusion of a lever in MAJ-1555 do not raise new questions of safety or effectiveness.

## 7. PERFORMANCE DATA

Bench testing was conducted to evaluate the performance and functional equivalence of the Olympus Single Use Biopsy Valve MAJ-1555 compared to the predicate device (Boston Scientific Seal™). Tests included assessments of attachment force, fixation during use, watertightness under various conditions, and compatibility with

endoscopic accessories. All tests met predefined acceptance criteria, demonstrating that the MAJ-1555 performs safely and effectively for its intended use. The results support the conclusion that the MAJ-1555 is substantially equivalent to the predicate device.

## 8. BIOCOMPATIBILITY

Biocompatibility testing for the Olympus Single Use Biopsy Valve MAJ-1555 was conducted in accordance with ISO 10993-1:2018 and FDA guidance on the use of ISO 10993 standards. The device is classified as a surface-contacting medical device with limited mucosal membrane contact (≤ 24 hours). Testing was performed using the identical biopsy valve from the MAJ-2287 kit.

The following tests were conducted:

- **Cytotoxicity** (Cytotoxicity (ISO 10993-5:2009, MEM Elution Test )
- **Sensitization** (ISO 10993-10:2021, Guinea Pig Maximization Test)
- **Irritation** (ISO 10993-23:2021, Intracutaneous Reactivity Test)

All tests passed the acceptance criteria.

The results demonstrate that the MAJ-1555 biopsy valve is biocompatible.

## 9. STERILIZATION AND SHELF LIFE

The Olympus Single Use Biopsy Valve MAJ-1555 is sterilized using gamma irradiation at a validated dose range of 25–43 kGy. Sterilization validation and packaging integrity were conducted in accordance with ISO 11137 and ISO 11607 standards.
Shelf-life testing was performed using accelerated aging methods to simulate a 3-year shelf life. The following evaluations were conducted post-aging:

- **Seal Width** (ISO 11607-1:2019, ISO 11607-2:2019): All samples met the minimum seal width requirement of ≥6 mm.
- **Seal Strength** (ASTM F88/F88M:2021): All samples exceeded the minimum required strength of 2.032 N/in.
- **Seal Integrity** (ASTM F3039-23 Method A): No dye penetration was observed, confirming intact seals.
- **Functional Testing**: Post-aging, the device maintained performance in attachment, fixation, watertightness, and compatibility with endoscopic accessories.

All test results met acceptance criteria, confirming that the MAJ-1555 maintains sterility and functional integrity throughout its labeled shelf life of 3 years.

## 10. SUBSTANTIAL EQUIVALENCE

Based on the intended use, technological characteristics, performance testing, and comparison to the predicate device, the Single Use Biopsy Valve MAJ-1555 raises no new issues of safety and effectiveness and are substantially equivalent to the predicate device Seal™ Single Use Biopsy Valve.

## 11. CONCLUSION

Based on the results of the comparison of the indications for use, technological characteristics, and performance testing of the Subject and Predicate devices, the Subject Single Use Biopsy Valve MAJ-1555 raises no new issues of safety and effectiveness, and the device is substantially equivalent to the Predicate device.