Febraury 22, 2026

Olympus Medical Systems Corp.
% Susan Lewandowski
Manager, Program Regulatory Affairs
Olympus Surgical Technologies Of The Americas
800 W Park Dr.
Westborough, Massachusetts 01581

Re: K253646
Trade/Device Name: Single Use Distal Cover MAJ-2315 (MAJ-2315)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDT
Dated: November 20, 2025
Received: November 20, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

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.	K253646

Please provide the device trade name(s).

Single Use Distal Cover MAJ-2315 (MAJ-2315)

Please provide your Indications for Use below.

The SINGLE USE DISTAL COVER MAJ-2315 has been designed to be attached to OLYMPUS endoscopes to cover the distal end of the insertion tube and around the forceps elevator.

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

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

510(k) Summary

1. General Information

Date Prepared: November 20, 2025

Applicant: Olympus Medical Systems Corporation
2951 Ishikawa-cho, Hachioji-shi, Tokyo Japan 192-8507
Establishment Registration No: 8010047

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: SINGLE USE DISTAL COVER MAJ-2315
Common Name: Duodenoscope and accessories
Classification: 876.1500 – Endoscope and accessories
Regulatory Class: II
Product Code: FDT (Duodenoscope, Accessories, Flexible/Rigid)
Device Panel: Gastroenterology & Urology

3. Predicate Device Information

SINGLE USE DISTAL COVER MAJ-2315 – Olympus K220587

4. Device Description

The Single Use Distal Cover MAJ-2315 has been designed to be attached to OLYMPUS endoscopes to cover the distal end of the insertion tube and around the forceps elevator. The MAJ-2315 is used as the distal cover for the EVIS EXERA III Duodenovideoscope Olympus TJF-Q190V. The MAJ-2315 is provided sterile and is discarded after use. The 510(k) communicates the change of the addition of the Attachment Tool to the MAJ-2315 and a minor manufacturing process change. The MAJ-2315 is pre-loaded into the Attachment Tool and is discarded once the MAJ-2315 is placed onto the distal end of the endoscope.

The subject device MAJ-2315 is minimally changed from the predicate device MAJ-2315 (K220587).

5. Intended Use/Indications for Use

The SINGLE USE DISTAL COVER MAJ-2315 has been designed to be attached to OLYMPUS endoscopes to cover the distal end of the insertion tube and around the forceps elevator.

6. Comparison of Technological Characteristics

Compared to the predicate device, the change is limited to the addition of the Attachment Tool and a minor manufacturing process change.

There are no changes to the indications for use, conditions of use, compatible components to be marketed/used with the device, device design or specifications for the MAJ-2315.

7. Summary of Non-Clinical Performance Data

Verification/validation activities were performed subsequent to a risk assessment evaluation of the addition of the Attachment Tool to the MAJ-2315 per the Olympus Quality Management System. Results of the following testing demonstrate that the changes to the MAJ-2315 does not adversely affect device performance:

- Performance Testing – Bench
- Sterilization and Shelf Life Testing

8. Summary of Clinical Performance Data

No clinical data were collected.

9. Conclusion

Based on the comparison of the indications for use, technological characteristics, and performance testing of the SINGLE USE DISTAL COVER MAJ-2315 and the predicate device, the changes described herein do not raise any new issues of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.