May 21, 2026

Olympus Medical Systems Corp.
% Susan Lewandowski
Manager, Program Regulatory Affairs
Olympus Corporation of the Americas
800 W. Park Dr.
Westborough, Massachusetts 01581

Re: K260580
Trade/Device Name: Single Use Reloadable Clip Applicator (HX-810LR, HX-810UR); Clip (HX-610-090, HX-610-135); Long Clip (HX-610-090L, HX-610-135L); Short Clip (HX-610-090S, HX-610-135S); Super Short Clip (HX-610-135XS)
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: February 20, 2026
Received: February 20, 2026

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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.	K260580

Please provide the device trade name(s).

Single Use Reloadable Clip Applicator (HX-810LR, HX-810UR);
Clip (HX-610-090, HX-610-135);
Long Clip (HX-610-090L, HX-610-135L);
Short Clip (HX-610-090S, HX-610-135S);
Super Short Clip (HX-610-135XS)

Please provide your Indications for Use below.

The Single Use Reloadable Clip Applicators HX-810 Series, Clip HX-610 Series, Long Clip HX-610 Series, Short Clip HX-610 Series and Super Short Clip HX-610-135XS have been designed to be used with an Olympus endoscope for endoscopic Clip placement within the gastrointestinal (GI) tract in adult patients only for the purpose of:

(1) Endoscopic marking,
(2) Hemostasis for
  (a) Mucosal/sub-mucosal defects < 3 cm,
  (b) Bleeding ulcers,
  (c) Arteries < 2 mm,
  (d) Polyps < 1.5 cm in diameter,
  (e) Diverticula in the colon,
(3) As a supplementary method, closure of GI tract luminal perforations < 20 mm that can be treated conservatively.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

OLYMPUS

510(k) Summary

1. General Information

Date Prepared: February 20, 2026

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

Contact: Seiko Yunoki

Correspondent: Olympus Corporation of the Americas
800 West Park Drive, Westborough, MA 01581

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

2. Device Information

Device Name: Single Use Reloadable Clip Applicator (HX-810LR, HX-810UR),
Clip (HX-610-090, HX-610-135),
Long Clip (HX-610-090L, HX-610-135L),
Short Clip (HX-610-090S, HX-610-135S),
Super Short Clip (HX-610-135XS)

Common Name: Hemostatic Metal Clip for the GI Tract

Classification: 876.4400 Hemorrhoidal Ligator

Regulatory Class: II

Product Code: PKL

Device Panel: Gastroenterology & Urology

3. Predicate Device Information

Single Use Reloadable Clip Applicator HX-810 series, Clip HX-610 series – Olympus K240617

4. Device Description

The Single Use Reloadable Applicator HX-810 series and Clip HX-610 series have been designed to be used with an Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract in adult patients. The devices are single use devices provided sterile to the end user. The HX-810 Applicators are sterilized by Ethylene Oxide Gas and the HX-610 Clips are sterilized by Gamma-ray radiation.

The Single Use Reloadable Applicators and Clips are used together. The clip connected to the hook portion of the applicator is controlled by the operation wire by the operator using the slider. The clip extended from the coil sheath opens to the maximum opening width when the slider the applicator is pulled towards the operator. Clipping is achieved when the slider to the applicator is pulled completely and a portion of the clip connector is broken. Upon completion, the clip and the applicator are no longer connected. Once the clipping is performed, the closure force of the clips remain until tissue necrosis occurs and the clip is excreted naturally.

The subject device Clip HX-610 series is minimally changed from the predicate device HX-610 series (K240617).

5. Intended Use/Indications for Use

The Single Use Reloadable Clip Applicators HX-810 series, Clip HX-610 series, Long Clip HX-610 series, Short Clip HX-610 series and Super Short Clip HX-610-135XS have been designed to be used with an Olympus endoscope for endoscopic Clip placement within the gastrointestinal (GI) tract in adult patients only for the purpose of:

1) Endoscopic marking,
2) Hemostasis for
    - **a.** Mucosal/sub-mucosal defects < 3 cm
    - **b.** Bleeding ulcers
    - **c.** Arteries < 2 mm
    - **d.** Polyps < 1.5 cm in diameter
    - **e.** Diverticula in the colon
3) As a supplementary method, closure of the GI tract luminal perforations < 20 mm that can be treated conservatively.

6. Comparison of Technological Characteristics

Compared to the predicate device, the change is limited to minor design changes to the Clip HX-610 series.

There are no changes to the indications for use, conditions of use, compatible components to be marketed/used with the device, or device specifications for the Clip HX-610 series.

7. Summary of Non-Clinical Performance Data

Verification/validation activities were performed after a risk assessment evaluation of the minor design changes to the Clip HX-610 series per the Olympus Quality Management System. Results of the following testing demonstrate that the changes to the Clip HX-610 series do not adversely affect device performance:

- Performance Testing – Bench
- Shelf-Life Testing

- Biocompatibility Testing

8. Summary of Clinical Performance Data

No clinical data was collected.

9. Conclusion

Based on the comparison of the indications for use, technological characteristics, and performance testing of the Clip HX-610 series 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.