July 11, 2024

Olympus Medical Systems Corp.
% Rebecca Walker
Regulatory Program Manager
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K240617
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

Dear Rebecca Walker:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 3, 2024. Specifically, FDA is updating the Indications for Use Form to correct the device trade name from "HX-81O" to "HX-810" as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shanil Haugen, OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices, 301-796-0301, Shanil.Haugen@fda.hhs.gov.

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

June 3, 2024

Olympus Medical Systems Corp.
% Rebecca Walker
Regulatory Program Manager
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K240617
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: March 5, 2024
Received: March 5, 2024

Dear Rebecca Walker:

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240617

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)

Indications for Use *(Describe)*
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 G1 tract luminal perforations < 20 mm that can be treated conservatively.

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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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared on: 2024-03-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Olympus Medical Systems Corp.
Applicant Address	2951 Ishikawa-cho Hachiochi-shi Tokyo 192-8507 Japan
Applicant Contact Telephone	+81 42-642-2111
Applicant Contact	Ms. Seiko Yunoki
Applicant Contact Email	seiko.yunoki@olympus.com
Correspondent Name	Olympus Corporation of the Americas
Correspondent Address	800 West Park Drive Westborough MA 01581 United States
Correspondent Contact Telephone	805-551-3023
Correspondent Contact	Ms. Rebecca Walker
Correspondent Contact Email	Rebecca.walker@olympus.com

Device Name

21 CFR 807.92(a)(2)

Device Trade 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	Hemorrhoidal ligator
Classification Name	Hemostatic Metal Clip For The Gi Tract
Regulation Number	876.4400
Product Code(s)	PKL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183590	Single Use Reloadable Clip Applicator, Clip, Long Clip, Short Clip	PKL

Device Description Summary

21 CFR 807.92(a)(4)

The instruments (AKA EZClip) 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.

The Single Use Reloadable Clip Applicators and Clips are single-use devices. The HX-810 series Applicators are sterilized by Ethylene Oxide Gas and the HX-610 series Clips are sterilized by Gamma-ray radiation.

The Single Use Reloadable Clip Applicators and Clips are used in a combined state. The clip connected to the hook portion of the applicator is controlled via operation wire by the operator using the slider. The clip protruded from the coil sheath opens to the maximum opening width when the slider of the applicator is pulled towards the operator. Clipping is achieved when the slider of the applicator is pulled completely and the 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 clips remains in place until tissue necrosis occurs, and the clip is excreted naturally.

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

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.

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

Indications for use are the same as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device and the predicate device have the same technological characteristics except for design modifications to the Single Use Reloadable Clip Applicator. The subject device has the following design modifications to the Single Use Clip Applicator:

1. Structure of operation wire. The operation wire has been coated with silicone oil and covered with an inner tube composed of PTFE. The outer dimensions of the operator wire and number of stranded wires have been decreased.

2. Structure inside the handle. Dimensional changes have been introduced due to the decreased outer diameter of the operator wire.

3. Patient contacting materials. Silicone oil and PTFE have been added to the operation wire assembly.

The differences between the subject and predicate devices have been validated and testing demonstrates the design modifications do not raise new questions of safety or efficacy and that the subject device is substantially equivalent to the predicate device.

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

Product performance testing was conducted on the modified Single Use Reloadable Clip Applicator (HX-810 Series) to demonstrate equivalency and ensure the device meets its intended use and design specifications after a shelf life of three (3) years. The performance tests were conducted on finished, sterilized devices, prior to and after simulated distribution and accelerated aging for the terminally sterilized medical device in accordance with ASTM F1980-16(2016). The following tests were performed:

1. Insertability
2. Clip opening width
3. Clip rotatability
4. Clip capability
5. Withdrawal from Endoscope
6. Mechanical integrity of clip assembly
7. Tensile Strength/coil to handle strength
8. Applicator repetition

Based on the risk analysis, the design modification to the Single Use Reloadable Clip Applicator (HX-810 Series) did not require additional MRI Testing, Package Integrity Testing or Human Factors Studies; therefore, testing provided under K183590 is hereby incorporated as reference to this submission. As there were no changes to the Clip (HX-610 Series), product performance testing was not repeated for the Clips.

The subject Single Use Reloadable Clip Applicators (HX-810 Series) and Clips (HX-610 Series) have satisfied the pre-defined acceptance criteria for each test item described in the test plan. Therefore, it is determined that the device is as safe, as effective, and performs as well as the predicate.