August 1, 2019

Olympus Medical Systems Corp.
Sheri L. Musgnung
Manager, Regulatory Affairs
Olympus Surgical Technologies America
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610

Re: K183590
Trade/Device Name: Single Use Reloadable Clip Applicator,
Clip, Long Clip, Short Clip, Super Short Clip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL
Dated: July 2, 2019
Received: July 5, 2019

Dear Sheri Musgnung:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for
Martha W. Betz, Ph.D.
Acting Assistant Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183590

Device Name
Single Use Reloadable Clip Applicator, Clip, Long Clip, Short Clip, Super Short Clip

Indications for Use *(Describe)*
The Single Use Reloadable Clip Applicators and Clips 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
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."

Date Prepared: July 30, 2019

Section 5
510(k) Summary

5.1 GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
192-8507

■ Contact Person: Sheri L. Musgnung
Olympus Surgical Technologies America
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-3147
Fax: 484-896-7128
Email: sheri.musgnung@olympus.com

5.2 DEVICE IDENTIFICATION

■ Device Name	■ Model 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

(Hereinafter, described collectively as "Single Use Reloadable Clip Applicators and Clips")

■ Common Name: Endoscopic Clipping Device
■ Regulation Number: 21CFR 876.4400
■ Regulation Name: Hemorrhoidal ligator
■ Regulatory Class: II
■ Product Code: PKL
■ Classification Panel: Gastroenterology/Urology

5.3 PREDICATE DEVICE AND REFERENCE DEVICE

■ **Predicate device**

Device name	Applicant	510(k) No.
Resolution Clip	Boston Scientific Corporation	K142973

■ **Reference device**

Device name	Applicant	510(k) No.
Endoscopic Clipping Device HX-5LR-1, HX-6UR-1 Standard Clip HX-600-090/135, Long Clip HX-600-090L, Short Clip HX-600-090S/135S	Olympus Optical Co., Ltd	K013066
HX-Y0003-L, HX-Y0003-U	Olympus Medical Systems Corp.	K123601

5.4 DEVICE DESCRIPTION

■ **General Description of the subject device**

The Single Use Reloadable Clip Applicators and Clips 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.

■ **Principle of Operation**

The subject devices are composed of the applicator and clip. The devices are used in a combined state. The clip that is attached to the applicator is controlled by the operator using the slider.

The clip 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.

5.5 INDICATIONS FOR USE

The Single Use Reloadable Clip Applicators and Clips 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.

5.6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The Single Use Reloadable Clip Applicators and Clips have the same intended use and similar technological characteristics and design as the predicate device except for the following main differences:

(1) Dimension and material of delivery system (clip applicator) and clip
(2) Clip reloadability
(3) Sterilization method of clip

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side-by-side comparison of the subject devices and the predicate device is provided below.

Item	Subject Device (SD)	Predicate Device (PD)
	HX-810, HX-610	Resolution Clip (K142973)
Indications for Use	The Single Use Reloadable Clip Applicators and Clips 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 Resolution™ Hemostasis Clipping Device is indicated for clip placement within the gastrointestinal (GI) tract for the purpose of: 1. Endoscopic marking 2. Hemostasis for: ■ Mucosal/sub-mucosal defects < 3 cm ■ Bleeding ulcers ■ Arteries < 2 mm ■ Polyps < 1.5 cm in diameter ■ Diverticula in the colon ■ Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection 3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel; and Anchoring to affix fully covered esophageal selfexpanding metal stents to the wall of the esophagus 4. As a supplemental closure method of luminal perforations < 20 mm that can be treated conservatively.
Model name	HX-810LR, HX-810UR, HX-610-090, HX-610-135 HX-610-090L, HX-610-135L, HX-610-090S, HX-610-135S, HX-610-135XS	M00522600, M00522601, M00522602, M00522610, M00522611, M00522612
Common name	Endoscopic Clipping Device	Endoscopic Clipping Device
Regulation Number	21CFR 876.4400	21CFR 876.4400
Regulation Name	Hemorrhoidal ligator	Hemorrhoidal ligator
Regulatory Class	II	II
Product Code	PKL	PKL

Item	Subject Device (SD)	Predicate Device (PD)
	HX-810, HX-610	Resolution Clip (K142973)
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital
Sterilization	HX-810:EOG (Marketed as a sterilized device) HX-610:Gamma radiation Marketed as a sterilized device	EOG
Reprocessing	Unknown	Unknown
Single-Use/ Reusable	HX-810: Single Use (multiple clipping to one patient) HX-610: Single Use	Single use
Reloadability	Yes	No
Material composition of patient-contact parts	[HX-810] Stainless steel Polytetrafluoroethylene Silver solder [HX-610] Stainless steel Polyphthalamide Liquid Crystal Polymer	Unknown
Duration and type of contact	[HX-810] Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours). [HX-610] Surface-contacting device in contact with mucous membrane and breached or compromised surfaces. The contact duration is prolonged exposure (>24 hours to 30 days).	Unknown

5.7 PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

(1) Sterilization/Shelf life testing

Sterilization/shelf life testing for the Single Use Reloadable Clip Applicators and Clips were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile". Accelerated aging test for the Single Use Reloadable Clip Applicators and Clips was conducted in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. The real-time aging test for three-years will be performed to demonstrate longer stability and support the results of the accelerated aging test.

(2) Biocompatibility testing

Biocompatibility testing for the Single Use Reloadable Clip Applicators and Clips were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

[HX-810]
- Cytotoxicity Study Using the Colony Assay
- Intracutaneous Study in Rabbits
- Guinea Pig Maximization Sensitization Test
- Systemic Toxicity Study in Mice
- Material-Mediated Pyrogenicity

[HX-610]
- Cytotoxicity Study Using the Colony Assay
- Intracutaneous Study in Rabbits
- Guinea Pig Maximization Sensitization Test
- Systemic Toxicity Study in Mice
- Material-Mediated Pyrogenicity
- Bacterial Reverse mutation Test
- In Vitro Chromosomal Aberration Assay
- Muscle Implantation Test
- Subchronic Toxicity Test
- Chemical characterization

(3) Performance testing - Bench

Bench testing for the Single Use Reloadable Clip Applicators and Clips as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

- Insertability
- Clip opening width
- Clip rotatability
- Clip capability
- Withdrawal from endoscope
- Applicator repetition
- Endoscope compatibility
- Clip tail length
- Retention capability
- MRI testing*
- Package integrity testing
- Mechanical testing

*MRI testing was conducted in accordance with various applicable ASTM standards, which demonstrated the device to be MRI conditional.

(4) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

(5) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

(6) Risk analysis

Risk analysis for the Single Use Reloadable Clip Applicators and Clips was conducted in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

5.8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the Single Use Reloadable Clip Applicators and Clips raise no new issue of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, efficacy and performance.