DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Olympus Optical Co., Ltd.
% Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
2 Corporate Center Drive
Melville, NY 11747-3157

JUL 27 2015

Re: K013066
Trade/Device Name: Rotatable Clip Fixing Devices HX-5/6-1
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: FHN, MND
Dated (Date on orig SE ltr): September 10, 2001
Received (Date on orig SE ltr): September 12, 2001

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of December 11, 2001

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013066

Device Name: Rotatable Clip Fixing Devices HX-5/6-1

Indications for Use:

Olympus Rotatable Clip Fixing Device HX-5/6-1 have been designed to be used with an Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract for the purpose of

(1) endoscopic marking
(2) hemostasis for
  (a) mucosal/sub-mucosal defects <3cm,
  (b) bleeding ulcers,
  (c) arteries <2mm,
  (d) polyps <1.5cm in diameter,
  (e) diverticula in the colon,
(3) anchoring to affix jejunal feeding tubes to the wall of the small bowel,
(4) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013066

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510(k) SUMMARY

Rotatable Clip Fixing Device HX-5/6-1

A. Submitter's Name, Address, Phone and Fax Numbers

1. Manufacturer of the subject devices

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjyuku Monolis Nishishinjyuku Shinjuku-ku, Tokyo, Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL (426)-42-5177 FAX (426)-46-5613

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Ms. Laura Storms-Tyler Olympus America Inc. Director, Regulatory Affairs Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name, Class, Classification Number and Predicate Devices

Device Name	: Olympus HX-5/6-1 Endoscopic Clipping Device Standard Clip HX-600-090 Standard Clip HX-600-135 Long Clip HX-600-090L Short Clip HX-600-090S Short Clip MAJ-458 Short Clip HX-600-135S
Common Name	: Endoscopic Clipping Device
Classification Name	: Endoscope and accessories
Class	: Class II
Classification Number	: 21CFR 876.1500
Predicate Device	: HX-5/6-1 Endoscopic Clipping Device #K963160 Olympus HX-5/6 Endoscopic Clipping Device #K990687

D. Description of the Device(s)

The HX-5/6-1 Endoscopic Clipping Device is available as a set consisting of the HX-5/6-1 Endoscopic Clipping Device main body and clips.

These clips are attached to the hook when the wire is advanced out of the distal end of the device. Applying tension to the control wire will "seat" a step on the clip onto the distal end of the stainless steel coil. The FEP tube sheath may then be advanced to cover the distal end of the coil and the attached clip. The device may then be inserted through the instrument channel of the appropriate endoscope.

When the device has been advanced to the area of interest, the outer sheath is retracted by moving the tube joint distally until an audible "click" is heard. When the control section slider is pulled proximally, the control wire is tensioned, and the clip is pulled into the clip body (pipe). Due to the shape of the clip itself, when the clip is pulled into the clip pipe, it will initially open wider. As it is pulled in even further, the clip pipe will force the clip arms to close on the target tissue and deploy.

E. Intended Use of the Device(s)

Olympus Rotatable Clip Fixing Device HX-5/6-1 have been designed to be used with an Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract for the purpose of

(1) endoscopic marking
(2) hemostasis for
  (a) mucosal/sub-mucosal defects <3cm,
  (b) bleeding ulcers,
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  (d) polyps <1.5cm in diameter,
  (e) diverticula in the colon,
(3) anchoring to affix jejunal feeding tubes to the wall of the small bowel,
(4) as a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the similar device, Rotatable Clip Fixing Devices HX-5/6-1 does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness.