

JUN 27 1997

K 963160

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**510(k) Summary
For The
Olympus HX-5/6-1 Endoscopic Clipping Device**

Device Name: Olympus HX-5/6-1 Endoscopic Clipping Device

Common/Usual Name: Endoscopic Clipping Device

Classification Name: Endoscopes and Accessories
21 CFR 876.1500

Predicate Devices: Olympus HX-2, HX-3, and HX-4 Clipping Devices

Contact Person: Subhash R. Patel
Olympus America, Inc.
Endoscope Division
2 Corporate Center Drive
Melville, NY 11747-3157
(516) 844-5481

Summary Preparation Date: March 26, 1997

Statement of Intended Use: The Olympus HX-5/6-1 Endoscopic Clipping Device is intended for endoscopic clip placement within the gastrointestinal (GI) tract for the purpose of endoscopic marking, hemostasis in the upper GI tract for mucosal/submucosal defects <3 cm, bleeding ulcers and arteries <2 mm, polyps <1.5 cm in diameter, and anchoring to affix jejunal feeding tubes to the wall of the small bowel. This device is not intended for the repair of GI tract luminal perforations.

Device Description: The Olympus HX-5/6-1 Endoscopic Clipping Device is specifically designed for endoscopic clipping for marking, hemostasis, and temporary anchoring within the GI tract. The Olympus HX-5/6-1 Endoscopic Clipping Device is based on the design of predicate clipping devices and is substantially equivalent in design, method of operation, and safety to these predicate devices.



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

March 25, 2015

Olympus America, Inc.
Subhash R. Patel
Regulatory Affairs Manager
Two Corporate Center Drive
Melville, NY 11747-3157

Re: K963160
Trade/Device Name: HX-5/6-1 Endoscopic Clipping Device
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: PKL
Dated (Date on orig SE ltr): April 24, 1997
Received (Date on orig SE ltr): May 2, 1997

Dear Subhash R. Patel,

This letter corrects our substantially equivalent letter of June 27, 1997.

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,

Joyce M. Whang -S

for 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

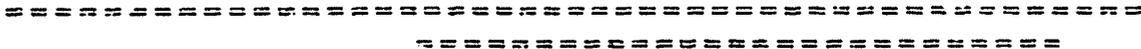
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K963160

Subject Device Name: Olympus HX-5/6-1 Endoscopic Clipping Device

Indications for Use: The subject device has been designed for endoscopic clip placement within the gastrointestinal (GI) tract for the purpose of endoscopic marking, hemostasis in the upper GI tract for mucosal/submucosal defects <3 cm, bleeding ulcers and arteries <2 mm, polyps <1.5 cm in diameter, and anchoring to affix jejunal feeding tubes to the wall of the small bowel. This device is not intended for the repair of GI tract luminal perforations.

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



Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Sathling

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use (per 21CFR 801.109) 510(k) Number K963160 OR Over-the-Counter Use _____
(Optional Format 1-2-96)