

K 964661

510(k) SUMMARY
OLYMPUS HX-20-1 ENDOSCOPIC LIGATOR

OCT 30 1997

Device Name: Olympus HX-20-1 Endoscopic Ligator

Common/Usual Name: HX-20-1 Endoscopic Ligator

Classification Name: Endoscope and Accessories
21 CFR 876.1500

Predicate Device: Endoscopic Ligators by C.R. Bard, Wilson-Cook, and Microvasive

Contact Person: Laura Storms-Tyler
Olympus America, Inc.
Endoscope Division
2 Corporate Center Drive
Melville, NY 11747-3157
(516) 844-5688

Summary Preparation Date: October 22, 1997

Statement of Intended Use:

Olympus HX -20-1 Endoscopic Ligator has been designed to be used with Olympus endoscopes in delivering a MAJ-254 Standard Ligation Loop or MAJ-340 Small Ligation Loop designed to prevent or control bleeding following polypectomy of pedunculated polyps.

Device Description:

The Olympus HX-20-1 Endoscopic Ligator is intended to deliver a MAJ-254 Standard Ligation Loop or MAJ-340 Small Ligation Loop to prevent or control bleeding following polypectomy of pedunculated polyps. The Olympus "EndoLoop" is substantially equivalent in intended use to endoscopic ligators marketed by Bard, Microvasive, and Wilson-Cook. The subject ligating device differs from these devices in that it operates via through-the-scope techniques.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 1997

Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Endoscopic Division
Olympus America, Inc.
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K964661
HX-20/21-1 Endoscopic Ligator
Dated: September 3, 1997
Received: September 4, 1997
Regulatory class: II
21 CFR §876.4400/Product code: 78 FHN and MND

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): Not assigned yet *K 964661*

Device Name: Olympus HX-20-1 Endoscopic Ligator

Indications for Use:

The Olympus HX -20-1 Endoscopic Ligator has been designed to be used with Olympus endoscopes in delivering a MAJ-254 Standard Ligation Loop or MAJ-340 Small Ligation Loop, designed to prevent or control bleeding following polypectomy of pedunculated polyps.

Robert P. Rathig

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number *K 964661*

Prescription Use
(Per 21 CFR 801.109)

Over-the-Counter Use _____