OCT 2 3 1998

K982725

510(k) SUMMARY

OLYMPUS MH-246R BALLOON SHEATH

Device Name:	Olympus MH-246R Balloon Sheath (for female reproductive tract)
Common/Usual Name:	Balloon Sheath
Classification Number & Name:	Class II, 21CFR892.1570, Diagnostic Ultrasonic Transducer Class II, 21CFR884.1690, Hysteroscope and accessories
Predicate Devices:	Olympus MH-246R (for GI use) K961048
Submitted By: (Contact Person)	Laura Storms-Tyler Olympus America Inc. Regulatory Affairs Two Corporate Center Drive Melville, New York 11747-3157 (516) 844-5688
Summary Preparation Date:	May 25, 1998

Statement of Intended Use

The MH-246R Balloon Sheath for female reproductive tract is designed to be used with the Olympus Ultrasonic Probe UM-2R/UM3R for intraluminal ultrasonic imaging of the female reproductive tract.

Device Description

The MH-246R Balloon Sheath for female reproductive tract consists of two sections - insertion section and connector section. The insertion section is constructed of a balloon with the light shielding cover, insertion tube, and adapter. The connector section consists of a connector body, probe locking ring, sheath locking ring, and irrigation port.

The insertion section is connected to the connector body through a sheath locking ring, while the ultrasonic probe is inserted into the balloon sheath through a probe locking ring. The water filled syringe is connected to the irrigation port via an extension tube and three-way stopcock. The insertion section with the balloon will be provided sterile and intended for single use only. The connector section can be reused after proper cleaning and sterilization as outlined in the instruction manual.

General Safety

When compared to the predicate devices, Olympus MH-246R Balloon Sheath does not incorporate any significant change in method of operation, material, or design that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 1998

Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Dr.
Melville, NY 11747-3157

Re: K982725
Olympus MH-246R Balloon Sheath, for Female Reproductive Tract Use
Dated: August 4, 1998
Received: August 5, 1998
Regulatory class: II
21 CFR 892.1570/Procode: 90 ITX

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 (Premarket 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 requirements, 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/dsma/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

510(k) Number (if known): K982725

Device Name: Olympus MH-246R Balloon Sheath
(for female reproductive tract)

Indications for Use:

Olympus MH-246R Balloon Sheath have been designed to be used with the Olympus Ultrasonic Probe UM-2R/UM-3R, for intraluminal ultrasonic imaging of the female reproductive tract.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982725