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DEC 11 1998

510(k) Summary
Olympus UM-2R/3R Ultrasonic Probe

Device Name:	Olympus UM-2R/3R Ultrasonic Probe and ancillary equipment for bronchial use
Common/Usual Name:	Olympus Ultrasonic Probes
Classification Number and Name:	Class II, 21 CFR 892.1570 Diagnostic Ultrasound Transducer Class II 21 CFR 874.4680 Bronchoscope and accessories
Predicate Devices:	Olympus EU-M30 (K951994) Olympus UM-2R/3R (K944610) Olympus EU-M20 (K926514) Olympus EU-M3 (K882061)
Submitted by:	Laura Storms-Tyler Olympus America Inc. Two Corporate Center Drive Melville, NY 11042-1179 (516) 844-5688
Summary Preparation Date:	June 26, 1998

Statement of Intended Use:

The Olympus UM-2R/3R Ultrasonic Probes have been cleared for use within the gastrointestional tract in 510(k) #K944610.

The Olympus UM-2R and UM-3R Ultrasonic Probes have been designed for use in combination with Olympus Endoscopic Ultrasound System for intraluminal sonographic imaging of the upper airways and tracheobronchial tree.

Device Description

In routine examination of the upper airways and tracheobronchial tree, there are situations where the physician prefers to perform an intensive examination, observation, and diagnosis of the upper airways and tracheobronchial tree. The conventional type bronchoscopes limit the physician's ability to access certain areas of interest. The UM-2R/UM-3R Ultrasonic Probes, when used with an endoscope offer transendoscopic access

to the upper airways and tracheobronchial tree. The 2.4 mm insertion tube of these probes can be advanced through strictures and anatomical ducts. The Olympus Ultrasonic Probes to be used in conjunction with bronchoscopes with a minimum channel size of 2.8 mm. The rotation of the transducer is controlled by a probe driving unit.

The UM-2R and UM-3R probes produce a B-mode scans using the de-aerated water immersion method and offer 360 degree mechanical/radial scanning of the tissue under observation, The outer diameter of the insertion tube is 2.4 mm and the length is 2050 mm. Both probes incorporate similar design, construction, intended use, and method of operation. The only difference between these two probes is that the UM-2R probe operates at 12 MHz and is compatible with both Olympus EU-M30, EU-M20 and EU-M3 Endoscopic Ultrasound Systems, while the UM-3R probe operates at 20 MHz and is compatible with the EU-M30 and the EU-M20 Endoscopic Ultrasound System. The Olympus EU-M30 Endoscopic Ultrasound Center was cleared for marketing in 510(k) # K951994. The Olympus EU-M20 Endoscopic Ultrasound System was cleared for marketing in 510(k) # K926514 and EU-M3 Endoscopic Ultrasound System was cleared for marketing in the 510(k) # K882061.

All components and associated equipment of the UM-2R / UM-3R Ultrasonic Probes will be marketed non-sterile and can be reprocessed as described in the Instruction Manual.

Safety

The Olympus UM-2R and UM-3R Ultrasound Probes are designed, manufactured, and tested in compliance with International Standard IEC 60601-1. The ultrasound characteristics of Olympus UM-2R and UM-3R Ultrasound Probes meet the requirements of the FDA's 510(k) Diagnostic Ultrasound Guidance for 1993 and 1985.

When compared to the predicate devices listed in the "Regulatory History" portion of this section, except for intended use, neither ultrasound probe incorporates any significant change in method of operation, material, or design that could affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 1998

Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
2 Corporate Center
Melville, NY 11747-5416

Re: K982323
Trade Name: Olympus UM-3R Ultrasonic Probes and associated ancillary equipment, for bronchial use
Regulatory Class: II/21 CFR 892.1570
Product Code: 90 ITX
Dated: June 30, 1998
Received: July 2, 1998

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 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). 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.

This determination of substantial equivalence applies to the following Ultrasound Systems intended for use with the Olympus UM-2R and UM-3R Ultrasonic Probes, as described in your premarket notification:

System Model Number

EU-M30
EU-M20
EU-M3

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 Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

This letter will allow you to begin marketing your device as described in your 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 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) 594-4591. 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for David A. Lyons

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

K982323

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		N	P							

N = new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

New indications = Intraluminal ultrasound for upper airways and tracheobronchial tree.

Previously cleared indications = Intraluminal ultrasound for gastrointestinal tract.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legrm

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

Prescription Use (Per 21 CFR 801.109)

510(k) Number K982323

510(k) Number (if known): K982323

Device Name: Olympus UM-2R / UM-3R Ultrasonic Probes and associated Ancillary Equipment (for bronchial use)

Indications for Use:

Olympus UM-2R and UM-3R Ultrasonic Probes have been designed for use in conjunction with Olympus Endoscopic Ultrasound System for intraluminal sonographic imaging of the upper airways and tracheobronchial tree.

(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 K982323