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ATTACHMENT 11.

510(k) Summary

510(k) SUMMARY
OLYMPUS UM-S30-25R ULTRASONIC PROBE AND ASSOCIATED
ANCILLARY EQUIPMENT FOR GASTROINTESTINAL TRACT

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 0426-42-5101 FAX 0426-46-2786

B. Name of Contact Person

Name:	Ms. Laura Storms-Tyler
Address, Phone and Fax Numbers:	Olympus America Inc. Endoscope Division Two Corporate Center Drive Melville, New York 11747-3157 TEL: (516) 844-5474 FAX: (516) 844-5416

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

Device Name:	Ultrasonic Probe UM-S30-25R Endoscopic Ultrasound Center EU-M30 Probe Driving Unit MH-240
Common Name:	Ultrasonic Probe
Classification Name:	21 CFR892.1570 Diagnostic Ultrasonic transducer

Predicate Device:

MODEL	NAME	510(k)#
UM-2R	Ultrasonic Probe	K944610
UM-3R	Ultrasonic Probe	K944610
EU-M30	Endoscopic Ultrasound Center	K982610(for urinary), K951994(for gastrointestinal tract), K982323(for bronchial use)4
MH-240	Probe Driving Unit	K982610(for urinary), K951994(for gastrointestinal tract), K982323(for bronchial use)
MH-240	Balloon Sheath	K944610 (for UM-2R/3R)

D. Description of the Device(s)

The Olympus UM-S30-25R Ultrasonic Probe has been designed to be used with an Olympus Endoscopic Ultrasound center, Probe Driving Unit and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract and surrounding organs. The probe is connected to the endoscopic ultrasound center through the probe driving unit. The probe is attached to the endoscope which allows the user to use probe. The probe is inserted into the patient through a channel of the endoscope. A probe driving unit controls the rotation of the transducer.

<Applicable endoscopes are as follows>

Flexible endoscope: inner channel is ϕ 2.8mm, ϕ 3.2mm, ϕ 4.2mm, ϕ 6mm and ϕ 5.5mm.

Rigid endoscopes : minimum capacity is 9Fr.

UM-S30-25R Ultrasound Probe produces a B-mode scans using the de-aerated water immersion method and balloon method. The probe offers 360 degree mechanical /radial scanning of the tissue under observation. The outer diameter of the insertion tube is 2.4mm and the length is 2050mm.

E. Intended Use of the Device(s)

The Olympus UM-S30-25R Ultrasonic Probe has been designed to be used with an Olympus Endoscopic Ultrasound center, Probe Driving Unit and an endoscope for intraluminal ultrasonic imaging of the gastrointestinal tract and surrounding organs.

F. Summary of the Technological Characteristics of the Device compared to the Predicate Device(s)

Ultrasonic Frequency

The ultrasonic frequency is changed to 30MHz.

G. Summary including a Brief Discussion of Non-clinical Tests and How their Results support Determination of Substantial Equivalence

1. Design

Endoscopic Ultrasound Center EU-M30 and Probe Driving Unit MH-240 have been designed, manufactured and tested in compliance with IEC 60601-1 and Revised 510(k) Diagnostics ultrasound Guidance for 1993,1995. It meets the requirements of IEC 60601-1 and Revised 510(k) Diagnostics ultrasound Guidance for 1993,1995.

Ultrasonic Probe UM-S30-25R has been tested to verify electromagnetic compatibility (EMC) with IEC 60601-1-2. It meets the requirements of IEC 6060-1-1-2.

2. Materials

The patient contacting materials are identical to predicate device.

H. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, the Olympus UM-S30-25R Ultrasonic probe and associated ancillary equipment do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Laura Storms-Tyler
Director, Regulatory Affairs and
Quality Assurance
Olympus America, Inc.
Two Corporate Center Drive
Melville, NY 11747-3157

Re: K994103
UM-S30-25R Ultrasonic Probe (Gastrointestinal Tract Use)
Regulatory Class: II
Product Code: 90 ITX/21 CFR 892.1570
Dated: March 30, 2000
Received: July 20, 2000

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 UM-S30-25R Ultrasonic Probe intended for use with the Olympus EU-M30 Endoscopic Ultrasound Center as described in your premarket notification.

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.

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 M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for 

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K994103

Device Name: Olympus UM-S30-25R Ultrasonic Probe and associated ancillary equipment for gastrointestinal tract

Indications for Use:

The OLYMPUS UM-S30-25R ULTRASONIC PROBE have been designed to be used with an OLYMPUS Endoscopic Ultrasound System for intraluminal sonographic imaging of the gastrointestinal tract and surrounding organs.

(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)

David A. Seymour

(Optional Format 1-2-96)

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

510(k) Number K994103

K994103

Diagnostic Ultrasound Indications for Use Form
OLYMPUS UM-S30-25R ULTRASONIC PROBE (Subject Device)

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		N								
Transrectal		N								
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)		N								

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

Additional Comments:
the gastrointestinal tract and the surrounding organs (GI use).

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (Per 21 CFR 801.109)

David A. Sigman
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K994103

K994103

Appendix F

Diagnostic Ultrasound Indications for Use Form
OLYMPUS EU-M30 ENDOSCOPIC ULTRASOUND CENTER (ancillary system)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis or 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		P								
Transrectal		P								
Transvaginal										
Transurethral		P								
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)		P								

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

Additional Comments:

Previously cleared indication : Intraluminal ultrasound for gastrointestinal tract and surround organs, upper air and tracheobronchial tree and urinary tract.

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
 Concurrency of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (Per 21 CFR 801.109)

F-3

David G. Johnson
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K994103