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K060475

January 25. 2006

SMDA 510(k) SUMMARY

EVIS EXERA Ultrasonic Bronchofibervideoscope, OYMPUS BF type UC160F-OL8

A. GENERAL INFORMATION

1. Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2851 Ishikawa-cho, Hachioji-shi, Tokyo, Japan, 192-8507 Registration No.: 8010047
2. Official Correspondent:	Laura Storms-Tyler Executive Director, Regulatory Affair and Quality Assurance Olympus America Inc Two Corporate Center Drive, Melville, NY ,11747-9058 ,USA TEL: 631-844-5688 FAX: 631-844-5554 E-mail:Laura.storms-tyler@olympus.com Registration No.: 2429304
3. Manufacturer :	OLYMPUS MEDICAL SYSTEMS CORP. 34-3 Hirai, Hinode-machi, Nishitama-gun, Tokyo, Japan,190-0182, Registration No.:3003637092

B. DEVICE IDENTIFICATION

1. Device Name:	EVIS EXERA Bronchofibervideoscope, OLYMPUS BF type UC160F-OL8
2. Common Name:	Bronchoscope
3. Regulation No.:	21 CFR 876.1500 / 892.1570
4. Regulation Name:	Bronchoscope (flexible or rigid) and its accessories
5. Regulatory Class:	II
6. Product Code:	KOG / ITX
7. Classification Panel:	Endoscope and accessories / Diagnostic Ultrasound Transducer
8. Prescription Status:	Prescription Device
9. Performance Standard:	None established under Section 514 of FDA for Bronchoscope

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2006

Olympus Corporation
% Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Road, Unit B7
TWINSBURG OH 44087

Re: K060475
Trade Name: EVIS EXERA Ultrasonic Bronchofibervideoscope OLYMPUS BF TYPE UC160F-OL8, Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: KOG and ITX
Dated: February 22, 2006
Received: February 23, 2006

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket 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 transducers intended for use with the Olympus BF-UC160F-OL8, as described in your premarket notification:

Transducer Model Number

Olympus BF-UC160F-OL8

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

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

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

EVIS EXERA Ultrasonic Bronchofibervideoscope OLYMPUS BF type UC160F-OL8
Diagnostic Ultrasound Indications for Use Form

Intended Use: Endoscopic real-time ultrasonic imaging, ultrasound guided needle aspiration and other endoscopic procedures as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N				B+M	Note 1
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 2)	N	N				B+M	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, and imaging for guidance of biopsy.

Note 2: Specification for "Other"

(1) the 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 (Per 21 CFR 801 Subpart D)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060475

OLYMPUS EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center
Diagnostic Ultrasound Indications for Use Form

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

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N				B+M	Note 1
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.) (Note 2)	N	N				B+M	Note 1
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and PowerMap™ Directional Color Power Doppler, and imaging for guidance of biopsy.

Note 2: Specification for "Other"

(1) the airways and tracheobronchial tree.

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