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AUG 1 8 2004

May 11.2004

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. Applicant, Submission Correspondent, Initial Importer, Official Correspondent

1. Applicant & Manufacture :

OLYMPUS CORPORATION
34-3 Hirai Hinode-machi,
Nishitama-gun, Tokyo, 190-0182 ,Japan
(Registration Number : 3003637092)

2. Submission Correspondent :

Masao Wada
OLYMPUS CORPORATION
2951 Ishikawa-cho, Hachiouji-shi, Tokyo
192- 8507, Japan
Telephone :81-426-42-2891
Facsimile : 81-426-42-2291
E-mail : m_wada@ot.olympus.co.jp
(Registration Number : 8010047)

3. Initial Importer :

OLYMPUS AMERICA INC.
Two Corporate Center Drive, Melville,
NY 11747-3157
(Registration Number : 2429304)

4. Official Correspondent :

Tina-Steffanie-Oak
Associate Manager Regulatory Affair
Clinical Monitor
OLYMPUS AMERICA INC.
Two Corporate Center Drive, Melville,
NY 11747-3157
Telephone :631-844-5477
Facsimile : 631-844-5416
E-mail :Tina, Steffainie-Oak@olympus.com
(Registration Number :2429304)

B. Device Name, Common Name

1. Common/Usual Name
Ultrasonic endoscope

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2. Device Name

- EVIS EXERA Ultrasonic Bronchofibervideoscope OLYMPUS BF type UC160F-OL8

3.Classification Name

	CFR Number	Product Code	Class
Endoscope and accessories	876.1500	KOG	II
Diagnostic Ultrasound Transducer	892.1570	ITX	II

C. Identification of the predicate or legally marketed device

The following devices are the predicate medical devices.

Device Name	#K
Ultrasonic Bronchofiberscope BF type UM40	K021204
EVIS EXERA Ultrasonic Bronchofibervideoscope BF typeXP160F	K033225
EU-C60 Compact Endoscopic ultrasound Center (EVIS EXERA Ultrasonic Gasrovideoscope GF type UC160P-OL5)	K010591
Ultrasonic Gasrovideoscope GF type UC160P-AT8	K031347

D. Device Description

1. Summary

The subject device has been designed to be used with the OLYMPUS EU-C60 EUS EXERA Compact Endoscopic ultrasound center, OLYMPUS video system center, light source, documentation equipment, display monitor, Endo-therapy accessories such as an aspiration biopsy needle.

The subject device is designed for endoscopic real-time ultrasonic imaging, for performing endoscopic ultrasound (EUS) guided fine needle aspiration (FNA) within the airways and trancheobronchial tree and the gastrointestinal tract.

2. Design

The subject device is designed to comply with the standards listed below.

IEC 60601-1
IEC 60601-1-1
IEC 60601-1-2
IEC 60601-2-18
CISPR11

3. Materials

The material for transducer surface of the subject device has a new patient-contacting material. The Biocompatibility test reports of the new material show that the new material is safe for its intended use.

E. Intended Use:

The intended use of these devices, as defined by FDA guidance documents is:

This instrument has been designed to be used with an OLYMPUS compact endoscopic ultrasound center, video system center, light source, documentation equipment, video monitor, Endo-therapy accessories and other ancillary equipment for endoscopic real time ultrasonic imaging, ultrasound guided needle aspiration and other endoscopic procedures within the airway and trancheobronchial tree and the gastrointestinal tract and surrounding organs.

F. Comparison Technological Characteristics:

The subject device operates identically to the predicate device (K010591) in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as ultrasonic images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis.

The subject device is basically identical to the predicate device (K021024), except that the subject device is equipped with the CCD in the control section, as well as the fiber bundle in the insertion tube. Images are transmitted through the fiber bundle and the CCD in the control section changes them to video signals. then, the endoscopic image is displayed on the monitor. This is identical with EVIS EXERA Ultrasonic Bronchofibervideoscope (K033225).

G. Conclusion

When compared to the predicate device, the BF type UC160F-OL8 does not incorporate any significant changes in the intended use, method of operation, or design that could affect safety and effectiveness. Therefore, clinical data is not necessary for evaluation of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2004

Olympus Corporation
% Mr. Derwyn Reuber
Vice President
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K042140
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: 78 KOG and 90 ITX
Dated: August 4, 2004
Received: August 9, 2004

Dear Mr. Reuber:

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 EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center, as described in your premarket notification:

Transducer Model Number

OLYMPUS BF Type 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 (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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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 Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for

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

Enclosures

4.3.2 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 gastrointestinal tract and the surrounding organs.

(2) 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 801.109)

David A. Lagzdins

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042140

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4.3 Indication for use :

4.3.1 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 gastrointestinal tract and the surrounding organs.

(2) 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 801.109)

David A. Lagerman

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

510(k) Number K042140

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