



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

JUL 27 2015

Re: K042140
Trade/Device 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
Regulatory Class: II
Product Code: ODG, FDS, EOQ and ITX
Dated (Date on orig SE ltr): August 4, 2004
Received (Date on orig SE ltr): August 9, 2004

Dear Mr. Reuber,

This letter corrects our substantially equivalent letter of August 18, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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. Ferguson

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

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4.3 Indication for use :

4.3.1 EVIS EXERA Ultrasonic Bronchofiberscope 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. [Signature]
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number

K042140

AUG 18 2004

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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
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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 tracheobronchial 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.