DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 27 2015

Olympus America, Inc.
% Mark Job
Program Manager
TUV Product Service
1775 Old Highway 8 N.W., Suite 104
New Brighton, MN 55112-1891

Re: K010591
Trade/Device Name: Olympus EU-C60 EUS EXERA
Compact Endoscopic Ultrasound Center
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ODG
Dated (Date on orig SE ltr): February 27, 2001
Received (Date on orig SE ltr): February 28, 2001

Dear Mr. Job,

This letter corrects our substantially equivalent letter of March 15, 2001.

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

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	N	N				B+M	Note 1
	Abdominal	N	N				B+M	Note 1
	Intra-operative (Abdominal organs and vascular)	N	N				B+M	Note 1
	Intra-operative (Neuro.)							
	Laparoscopic	N	N				B+M	Note 1
	Pediatric	N	N				B+M	Note 1
	Small Organ (breast, thyroid, testicles.)	N	N				B+M	Note 1
	Neonatal Cephalic	N	N				B+M	Note 1
	Adult Cephalic							
	Trans-rectal	N	N				B+M	Note 1
	Trans-vaginal	N	N				B+M	Note 1
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N				B+M	Note 1
	Musculo-skel. (Convent.)	N	N				B+M	Note 1
	Musculo-skel. (Superfic.)	N	N				B+M	Note 1
	Other (spec.) (Note2)	N	N				B+M	Note 1
Cardiac	Cardiac Adult	N	N				B+M	Note 1
	Cardiac Pediatric	N	N				B+M	Note 1
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N				B+M	Note 1
	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Note 2:

(1) the gastrointestinal tract and the surrounding organs.

(2) the airways and tracheobronchial tree.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: ICT/7-4 7.0-4.0 MHz Intracavitary Transducer

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	P	P				B+M	Note 3
	Abdominal							
	Intra-operative (Abdominal organs and vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P				B+M	Note 3
	Trans-vaginal	P	P				B+M	Note 3
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

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

Additional Comments:

Note 3: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: L38/10-5 10.0-5.0 MHz Linear Array

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	P	P				B+M	Note 3
	Abdominal	P	P				B+M	Note 3
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note 3
	Intra-operative (Neuro.)							
	Laparoscopic	P	P				B+M	Note 3
	Pediatric	P	P				B+M	Note 3
	Small Organ (breast, thyroid, testicles.)	P	P				B+M	Note 3
	Neonatal Cephalic	P	P				B+M	Note 3
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P				B+M	Note 3
	Musculo-skel. (Superfic.)	P	P				B+M	Note 3
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P				B+M	Note 3
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel.	P	P				B+M	Note 3
	Other (spec.)							

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

Additional Comments:

Note 3: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: C60/5-2 5.0-2.0 MHz Curved Array

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	P	P				B+M	Note 3
	Abdominal	P	P				B+M	Note 3
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note 3
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P				B+M	Note 3
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P				B+M	Note 3
	Cardiac Pediatric	P	P				B+M	Note 3
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

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

Additional Comments:

Note 3: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: C15/4-2 MHz Curved Array

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	P	P				B+M	Note3
	Abdominal	P	P				B+M	Note3
	Intra-operative (Abdominal organs and vascular)	P	P				B+M	Note3
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P				B+M	Note3
	Small Organ (breast, thyroid, testicles.)	P	P				B+M	Note3
	Neonatal Cephalic	P	P				B+M	Note3
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P				B+M	Note3
	Musculo-skel. (Superfic.)							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P				B+M	Note3
	Cardiac Pediatric	P	P				B+M	Note3
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P				B+M	Note3
	Other (spec.)							

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

Additional Comments:

Note3: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy previously cleared through 510(k) K003399.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: Olympus GF TYPE UC160P-OL5
EUS EXERA Ultrasonic Gastrovideoscope

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; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Note 2:

(1) the gastrointestinal tract and the surrounding organs.

(2) the airways and tracheobronchial tree.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010591

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

Transducer: Olympus GF TYPE UCT160-OL5
EUS EXERA Ultrasonic Gastrovideoscope

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; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and **PowerMap™ Directional Color Power Doppler**, 3-D Imaging, Harmonic Imaging, and imaging for guidance of biopsy.

Note 2:

(1) the gastrointestinal tract and the surrounding organs.

(2) the airways and tracheobronchial tree.

Prescription Use (Per 21 CFR 801.109)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010591

K010591

MAR 1 5 2001

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. Submitter's name, address, telephone number, initial importer, contact person

1. Manufacturer of the subject device

Name & Address of Manufacturer;	Olympus Optical Co,. Ltd. 2-3-1 Shinjukuku Monolis Nishi-Shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration Number :	810047
Address, Phone and Fax Of R & D Department Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-2891 FAX 81-426-46-5613

2. Initial Importer

Name : Address :	Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157 TEL 516-844-5688 FAX 516-844-5416

3. Name of Contact Person

Name :	Tsuyoshi Yanai Manager Regulatory Affairs Quality Assurance Department Endoscope Division
Address, Phone and Fax :	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 TEL 81-426-42-2891 FAX 81-426-46-5613

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B. Device Name, Common Name

1. Common/Usual Name
Diagnostic Ultrasound System with Accessories

2. Device Name
Olympus EU-C60 EUS EXERA Compact Endoscopic Ultrasound Center

3.Classification Name

	FR Number	Product Code	Class
Bronchoscope and accessories	874.4680	KIT	II
Endoscope and accessories	876.1500	KOG	II
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN	II
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO	II
Diagnostic Ultrasound Transducer	892.1570	ITX	II

C. Identification of the predicate or legally marketed device
The following devices information demonstrates that this device is substantially equivalent to a legally marketed ,predicate medical device.

1. Ultrasound System

Device Name	#K
SonoSite™ Hand-Carried Ultrasound System	K003399
SonoSite SonoHerat™ Hand-Carried Echocardiography System	K994096
Advanced Technology Laboratories(ALT) HDI 5000 Ultrasound System	K961459

2. Ultrasonic Gastrovideoscope

Device Name	#K
Olympus GF Type UM30P Ultrasonic Gastrofiberscope	K963023
Olympus GF Type UM130 Ultrasonic Gastrovideoscope	K971660
Olympus UM-2R/UM-3R Ultrasonic Probes	K982323
Olympus BF Type 240 Bronchovideoscopes	K963033
Olympus GIF-1T140 Video Gastroscope	K954451
Pentax FG-36UX, Ultrasound Upper GI Fiberscope	K961974

D. Device Description

1. Summary

The EU-C60 is a general purpose, compact, software-controlled, diagnostic ultrasound system. The EU-C60 has compatibility with SonoSite transducers (such as abdominal or intracavital transducers) and Olympus Ultrasound videoscope. Its function is to acquire ultrasound data and display it on a monitor in several modes.
(2D, Color Power Doppler, PowerMap™ Directional Color Power Doppler, or in a combination of modes.)
The EU-C60 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information used for clinical diagnostic purposes.
The GF-UC160P-OL5/GF-UCT160-OL5 give the operator the ability to perform Endocopic Ultrasound(EUS) guided fine needle aspiration(FNA).

2. Design

The EU-C60 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 of Balloon3 is 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 uses of the EU-C60, as defined by FDA guidance documents, are:

Fetal - OB/GYN	Musculo-skeletal (conventional)
Laparoscopic	Musculo-skeletal (superficial)
Intraoperative (abdominal organs and vascular)	Neonatal Cephalic
Abdominal	Pediatric
Small Organ (breast, thyroid, testicle)	Cardiac-(adult and pediatric)
Trans-vaginal	Trans-esophageal (non-cardiac)
Trans-rectal	Peripheral Vessel
Other 1) Gastrointestinal tract and the surrounding Organs 2) The airways and tracheobronchial tree	

F. Technological Characteristics:

This device operates identically to the predicate devices 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 images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis.

Technological Characteristics of this device is identical to the predicated devicesIdentified in item 3.