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

MAY 17 2017

Olympus America, Inc.
c/o Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Services
70 Cadman Hill Road
Boxborough, MA 01719

Re: K021204
Trade/Device Name: Olympus BF Type UM40 Ultrasonic Bronchofiberscope
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: PSV, ITX, ODG
Dated: April 15, 2002
Received: April 16, 2002

Dear Mr. Sherratt,

This letter corrects our substantially equivalent (SE) letter of May 1, 2002 and our subsequent corrected SE letter of July 27, 2015.

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Eric A. Mann -S
2017.05.17 14:12:01 -04'00'

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.3.1 Indications for Use Form for Ultrasonic Bronchofiberscope OLYMPUS BF TYPE UM40

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									
	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										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Note1		N								

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

Additional Comments:

Note1: Specification for "Other"

Intraluminal ultrasound for upper 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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021204

4.3.1 Indications for Use Form For Olympus EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER With Olympus GF Type UM40 Ultrasonic Endoscopic Transducer

Diagnostic Ultrasound Indications for Use Form

Intended Use of new transducer: Intraluminal ultrasound for upper airways and tracheobronchial tree

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		P								
Transurethral		P								
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Other (specify)		P								

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

Additional Comments: Olympus EU-M60 EUS EXERA Endoscopic Ultrasound Center Previously cleared for use for Intraluminal ultrasound for upper airways and tracheobronchial tree under K011886

Specification for "Other": Gastrointestinal tract, biliary, pancreatic duct and surrounding organs, Intraluminal ultrasound for upper airways and tracheobronchial tree, urinary tract, female reproductive tract.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021204

4.3.1 Indications for Use Form For Olympus EU-M30 ENDOSCOPIC ULTRASOUND CENTER With Olympus GF Type UM40 Ultrasonic Endoscopic Transducer

Diagnostic Ultrasound Indications for Use Form

Intended Use of new transducer: Intraluminal ultrasound for upper airways and tracheobronchial tree

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										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Other (specify)		P								

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

Additional Comments: Olympus EU-M30 Endoscopic Ultrasound Center Previously cleared for use for Intraluminal ultrasound for upper airways and tracheobronchial tree with transducer UM 2R/3R under K982323

Specification for "Other": Gastrointestinal tract, biliary, pancreatic duct and surrounding organs. Cleared under K982323

(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))

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021204

K021204

MAY 01 2002

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 Regulatory Affairs Manager, Olympus Optical Co,. Ltd.
Address, Phone and Fax:	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-2891 FAX 81-426-46-5613

B. Device Name, Common Name

1. Common/Usual Name
Ultrasonic endoscope

2. Device Name
- Ultrasonic Bronchofiberscope OLYMPUS BF TYPE UM40

3.Classification Name

	FR 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 information demonstrates that this device is substantially equivalent to a legally marketed, predicate medical device.

Device Name	#K
EUS EXERA Ultrasonic Gastrovideoscope OLYMPUS GF TYPE UM160	K011886
Olympus UM-2R/ 3R Ultrasonic Probes and associated ancillary equipment (for bronchial use)	K982323
BF-240/P240/1T240 Bronchovideoscope & Accessories	K963033
Bronchoscope BF-N20	K910423

D. Device Description

1. Summary

This subject device has been designed to be used with an OLYMPUS endoscopic ultrasound center, light source, documentation equipment, display monitor, endo-therapy accessories and other ancillary equipment for endoscopic ultrasonic imaging of the upper airways and trancheobronchial tree.

2. Design

This 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 Insertion Tube Outer Surface of this 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 this subject device, as defined by FDA guidance documents, is:

Other 1)Intraluminal ultrasound for upper airways and tracheobronchial tree

F. Technological Characteristics:

This device operates identically to the predicate devices in that the transducer of the endoscope that is inserted into the body cavity mechanically scans the targeted site. The piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as images.

Technological Characteristics of this device is identical to the predicated devices identified in item C.