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 Medical Systems Corporation
Ms. Laura Storms-Tyler
Director, Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway, P.O. Box 610
Center Valley, PA 18034-0610

Re: K070983
Trade/Device Name: XBF-UC180F-DT8 Ultrasonic Bronchofibervideoscope
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: PSV, IYN, ITX
Dated: May 29, 2007
Received: May 31, 2007

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent (SE) letter of July 5, 2007 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 14:13:13 -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 Diagnostic Ultrasound Indications for Use Form

K070983

OLYMPUS XBF- UC180F-DT8 ULTRASONIC BRONCHOFIBERVIDEOSCOPE used with the ALOKA SSD-Alpha 5/10 ULTRASOUND SYSTEM

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)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (specify)									
	Intraoperative (Neuro.)									
	Laparoscopic									
	Pediatric									
	Small Organ (specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)		N	N	N		N	N	(Note 2)	
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Other (spec.) (Note 1)		N	N	N		N	N	(Note 2)	
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: Specification for "Other" :
Airways and tracheobronchial tree.

Note 2: "Combined mode operation" includes: B/M,B/PWD,B/CD/PWD

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K070983

4.3.1 Diagnostic Ultrasound Indications for Use Form

K070983

7.5 MHz linear array transducer
used with the ALOKA SSD-Alpha 5/10 ULTRASOUND SYSTEM

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)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (specify)									
	Intraoperative (Neuro.)									
	Laparoscopic									
	Pediatric									
	Small Organ (specify)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)		P	P	P		P	P	(Note 2)	
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Other (spec.) (Note 1)		P	P	P		P	P	(Note 2)	
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: Specification for "Other" :
Airways and tracheobronchial tree.

Note 2: "Combined mode operation" includes: B/M,B/PWD,B/CD/PWD

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K070983

K070993

510(k) SUMMARY

JUL - 5 2007

March 26, 2007

1 General Information

		XBF-UC180F-DT8	SSD-Alpha 5 / 10
4.2.1	**Manufacture's Name:**	OLYMPUS MEDICAL SYSTEMS CORP. HINODE PLANT	ALOKA CO., LTD.
	Address:	34-3 Hirai Hinode-Machi, Nishitama-gun, Tokyo 190-0182, Japan	**6-22-1, Mure Mitaka-Shi,** Tokyo 181-8622, Japan
	Corresponding Official:	Laura Storms-Tyler Executive Director Regulatory Affairs & Quality Assurance	Richard J Cehovsky RA/QA Coordinator
	Address:	Olympus America Inc. 3500 Corporate Parkway PO Box 610 Center Valley, PA 18034-0610,	ALOKA CO. LTD USA 10 Fairfield blvd. Wallingford, CT 06492
	Telephone:	484-896-5688	203-269-5088
	Facsimile:	484-896-7128	
	E-mail:	Laura.storms-tyler@olympus.com	
	Applicant's Name:	OLYMPUS MEDICAL SYSTEMS CORP.	
	Address:	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507	
4.2.2	**Initial Distributor Name/Title/Firm:**	Olympus America Inc.	
	Address:	3500 Corporate Parkway PO Box 610 Center Valley, PA 18034-0610,	
	Telephone:	484-896-5688	

2 Device Identification

■ Device Trade Name:
OLYMPUS XBF-UC180F-DT8 ULTRASONIC BRONCHOFIBERVIDEOSCOPE used with the ALOKA SSD-Alpha 5/10 ULTRASOUND SYSTEM

■ Common Name: Ultrasonic Endoscope

Regulation Number: 892.1570 Diagnostic Ultrasound Transducer
892.1550 Ultrasonic Pulsed Doppler Imaging System
876.1500 Endoscope and Accessories

■ Regulatory Class: II

■ Product Code: 90-ITX/78-KOG/90IYN

3 Predicate Device Information

■ Ultrasonic Endoscope

Subject device	Predicate device	
	Name	Control number
XBF-UC180F-DT8 ULTRASONIC BRONCHOFIBERVIDEOSCOPE	BF-UC160F-OL8 EVIS EXERA ULTRASONIC BRONCHOFIBERVIDEOSCOPE	K042140
SSD-Alpha 5	ALOKA SSD-ALPHA 5 ULTRASOUND SYSTEM	K041916
SSD-Alpha 10	ALOKA SSD-ALPHA 10 ULTRASOUND SYSTEM	K043196

4 Device Description

OLYMPUS XBF- UC180F-DT8 ULTRASONIC BRONCHOFIBERVIDEOSCOPE has been designed to be used with the SSD-Alpha5 (K041916) and SSD-Alpha10(K043196) diagnostic ultrasound systems (ALOKA CO.,LTD.), video system center, light source, documentation equipment, display monitor, and endo-therapy accessories such as aspiration biopsy needle.
The subject device is designed for endoscopic real-time ultrasound imaging, for performing endoscopic ultrasound (EUS) guided fine needle aspiration (FNA) within the airway, tracheobronchial tree, esophagus, and surrounding organs.

5 Indications for Use

The indications for use of OLYMPUS XBF- UC180F-DT8 ULTRASONIC BRONCHOFIBERVIDEOSCOPE used with the ALOKA SSD-Alpha 5/10 ULTRASOUND SYSTEM are as follows:

- Transesophageal(non-cardiac)
- Airways and tracheobronchial tree

6 Comparison of Technological Characteristics

When the OLYMPUS XBF- UC180F-DT8 ULTRASONIC BRONCHOFIBERVIDEOSCOPE used with the ALOKA SSD-Alpha 5/10 ULTRASOUND SYSTEM is compared to its predicate device, the device does not incorporate any significant changes in its intended use, method of operation, material or design that could affect the safety and effectiveness, Technological characteristics of ALOKA SSD-ALPHA 5/10 ULTRASOUND SYSTEM is identical to the predicate devices identified in above item 3.