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

Olympus Medical Systems Corporation
% Ms. Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway, PO Box 610
Center Valley, PA 18034-0610

JUL 27 2010

Re: K093395
Trade/Device Name: Olympus GF Type UCT180, Olympus GF Type UST180
Evis Exera II Ultrasound Gastrovideoscope used with
ALOKA SSD-α 10 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, ODG and NWB
Dated (Date on orig SE ltr): May 26, 2010
Received (Date on orig SE ltr): May 27, 2010

Dear Ms. Kluesner,

This letter corrects our substantially equivalent letter of June 17, 2010.

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

Indications for Use

510(k) Number (if known): K093395

Device Name: OLYMPUS GF-UCT180

Indications For Use:

This instrument has been designed to be used with an Olympus universal endoscopic ultrasound center or a diagnostic ultrasound system (ALOKA CO. LTD), video system center, light source, documentation equipment, monitor, EndoTherapy accessories and other ancillary equipment.

This instrument is designed for endoscopic real-time ultrasound imaging, ultrasound guided needle aspiration and other endoscopic procedures within the upper gastrointestinal tract and surrounding organs.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093395

1.3.1 Diagnostic Ultrasound Indications for Use Form

OLYMPUS GF TYPE UCT180
ULTRASOUND GASTROVIDEOSCOPE
used with the ALOKA SSD-α10 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		N	N	N		N	N		
	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		
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic.)									
	Intravascular									
	Other (spec.) (Note 1)		N	N	N		N	N		
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (card.)									
	Trans-esophageal (card.)									
	Intra-cardiac									
	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" :

Gastrointestinal Tract and Surrounding Organs

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093395

ULTRASOUND SYSTEM SSD-α10

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		P	P	P		P	P	(Note 3)	
	Abdominal		P	P	P		P	P	(Note 3)	
	Intra-operative (specify) (Note 4)		P	P	P		P	P	(Note 3)	
	Intraoperative (Neuro.)									
	Laparoscopic									
	Pediatric		P	P	P		P	P	(Note 3)	
	Small Organ (specify) (Note 4)		P	P	P		P	P	(Note 3)	
	Neonatal Cephalic		P	P	P		P	P	(Note 3)	
	Adult Cephalic									
	Trans-rectal		P	P	P		P	P	(Note 3)	
	Trans-vaginal		P	P	P		P	P	(Note 3)	
	Trans-urethral									
	Trans-esoph. (non-Card.)		P	P	P		P	P	(Note 2)	
	Musculo-skel. (Convent.)		P	P	P		P	P	(Note 3)	
	Musculo-skel. (Superfic.)									
	Other (spec.) (Note 1)		P	P	P		P	P	(Note 2)	
Cardiac	Cardiac		P	P	P		P	P	(Note 3)	
Peripheral Vessel	Peripheral vessel		P	P	P		P	P	(Note 3)	
	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, Upper Gastrointestinal Tract and Surrounding Organs

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

Note 3: Specification for "Combined mode operation" includes :

B/M, P/PWD, M/CD, B/CD/PWD, B/CWD, B/CD/CWD

Note 4: Specification for "Small Organ" and "Intraoperative" :

Small Parts-breast/ testes/ thyroid,

Intra-operative-liver/ pancreas/ gall-bladder/ abdominal, gynecological, fetal, neonatal, cardiac.

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093955

K093395

JUN 17 2010

510(k) SUMMARY

March 9, 2010

1 General Information

		GF-UCT180	SSD-α 10
1.2.1	**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:	Stacy Abbatiello Kluesner, RAC 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:	484-896-5405	203-269-5088
	Facsimile:	484-896-7128	
	E-mail:	stacy.kluesner@olympus.com	
	Applicant's Name:	OLYMPUS MEDICAL SYSTEMS CORP.	
	Address:	2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507	
1.2.2	**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:

EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT180

■ Common Name: Ultrasonic Endoscope

Regulation Number: 892.1570 Diagnostic Ultrasound Transducer
892.1550 Ultrasonic Pulsed Doppler Imaging System
892.1560 Ultrasonic Echo Imaging System
876.1500 Endoscope and Accessories

■ Regulatory Class: II

■ Product Code: ITX/ IYN/ KOG/ NWB/ IYO

3 Predicate Device Information

■ Ultrasonic Endoscope

Subject device	Predicate devices	
	Name	Control number
GF-UCT180 EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE	GF-UC140P-AL5 ULTRASONIC GASTROVIDEOSCOPE	K011314
SSD-α 10	ALOKA SSD-α 10 ULTRASOUND SYSTEM	K043196

4 Device Description

OLYMPUS GF-UCT180 EVIS EXERA II ULTRASOUND GASTRO VIDEOSCOPE have been designed to be used with the SSD-α10(K043196) diagnostic ultrasound systems (ALOKA CO.,LTD.), video system center, light source, documentation equipment, monitor, Endo-Therapy accessories such as aspiration biopsy needle and other ancillary equipment.
The subject devices are designed for endoscopic procedures within the upper gastrointestinal tract and surrounding organs.

5 Indications for Use

This instrument has been designed to be used with an Olympus universal endoscopic ultrasound center or a diagnostic ultrasound system (ALOKA CO. LTD), video system center, light source, documentation equipment, monitor, EndoTherapy accessories and other ancillary equipment.
This instrument is designed for endoscopic real-time ultrasound imaging, ultrasound guided needle aspiration and other endoscopic procedures within the upper gastrointestinal tract and surrounding organs.

6 Comparison of Technological Characteristics

When the OLYMPUS GF-UCT180 used with the ALOKA SSD-α10 ULTRASOUND SYSTEM is compared to its predicate devices, 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-α10 ULTRASOUND SYSTEM is identical to the predicate devices identified in above item 3.