JUL 1 - 2005

K051541

Date: _____

510(K) Summary

Olympus GF-UE160-AL5 Endoscope used with Aloka Model SSD- 5000 Diagnostic Ultrasound System

This summary statement complies with 21 CFR, section 807.92 as amended March 14, 1995.

This premarket notification has been submitted by Olympus American, Inc. and covers the Olympus GF-UE160-AL5 endoscope used with the Aloka SSD-5000 diagnostic ultrasound system.

1. GENERAL INFORMATION

Applicant:

Submission Correspondent:
Laura Storms-Tyler
Director, Regulatory Affairs and Quality Assurance
Olympus America Inc.
Two Corporate Center Drive, Melville, NY 11747-9058
Phone: 631-844-5688
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Official Correspondent:
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Two Corporate Center Drive, Melville, NY 11747-9058
Phone: 631-844-5688
Fax: 631-844-5554
Establishment Registration No.: 2429304

2. DEVICE IDENTIFICATION

Trade/Common Name: The proprietary name is the Olympus GF-UE160-AL5 Gastro-video Endoscope used with the Aloka SSD-5000 Diagnostic Ultrasound System. The common name for this type of device is an Ultrasound Gastro-video Scope.

Regulation Number/Name: The items in this submission are covered under the following classification:

90 IYN	Ultrasonic Pulsed Doppler Imaging System	21 CFR 892.1550
90 ITX	Diagnostic Ultrasound Transducer	21 CFR 892.1570
90 IYO	Ultrasonic Pulsed Echo Imaging System.	21 CFR 892.1560
70 FDF	Endoscope and accessories	21 CFR 876.1500

The above have been classified as regulatory Class II.

510(K) Summary

3. Predicate Devices:
The Olympus GF-UE160-AL5 Endoscope is substantially equivalent to the Olympus GF-UC140P-AL5 Endoscope (K011314) and the GF-UM130 Endoscope (K971660). Both predicates share common indications and some features.

4. Device Description: The Olympus GF-UC140P-Al5 is an electronic radial scan ultrasound endoscope providing a 360° view angle.

5. Intended Use:
The Olympus GF-UE160-AL5 Ultrasonic Endoscope is intended to be used for endoscopic ultrasonic imaging of the gastrointestinal wall, bile and pancreatic ducts and surrounding organs. It is to be used with the Aloka SSD-5000 (K033311) Diagnostic Ultrasound system and various other video and light source accessories.

6. Comparison of Technological Characteristics:

Below is the comparison table between the subject device and its predicate devices

Specifications	Subject Device	Predicate Devices	
	GF-UE160-Al5	GF-UC140P-Al5 (K011314)	GF-UM130 (K971660)
Optical Characteristics:			
Field of View:	100° (video)	Same	Same
Direction of View:	55° forward-oblique	Same	Same
Depth of Field:	3~100mm	Same	Same
Outer Diameter of Distal End	ø 13.8mm	ø 14.2mm	ø12.7mm
Outer Diameter of Insertion Tube	ø 11.8mm	Same	ø 10.5mm
Angulations:			
Up:	130°	Same	Same
Down:	90°	Same	Same
Left:	90°	Same	Same
Right:	90°	Same	Same
Working Length	1250mm	Same	Same
Instrument Channel	ø 2.2mm	ø 2.8mm	ø 2.2mm
Contact Method	Ballon Method/De-Aerated Water Immersion Method	Same	Same

8. Conclusion:

When the GF-UE160-AL5 is compared to its predicates, the device does not incorporate any significant changes in intended use, method of operation, material or design that could affect the safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 - 2005

Olympus America, Inc.
% Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K051541
Trade Name: Olympus GF-UE160-AL5 Endoscope used with the Aloka SSD-5000 Diagnostic Ultrasound System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: FDF and ITX
Dated: June 9, 2005
Received: June 10, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Aloka SSD-5000 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

GF-UE160-AL5

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for use statement

510(K) Number (if known):

Device Name: Olympus GF-UE160-AL5 Endoscope used with the Aloka SSD-5000 Diagnostic Ultrasound System

Indications For Use:

The Olympus GF-UE160-AL5 is an ultrasonic gastro video endoscope to be used with an Aloka diagnostic ultrasound system, video system center, light source, video monitor, endo-therapy accessories for endoscopic ultrasound imaging of the gastrointestinal wall, bile and pancreatic ducts and surrounding organs.

The Aloka SSD-5000 (K033311) is an all-digital diagnostic ultrasonic scanner with a digital beam former supporting gray scale, spectral Doppler and Color Flow imaging. Depending on the probe, the Aloka SSD-5000 may be used for diagnostic ultrasound imaging in Cardiac, Gynecological, Neurological, Obstetrical, Neonatal, Pediatric, Perinatal, Radiological, Vascular, Urological, Trauma and Surgical applications. The Aloka SSD-5000 is a Track 3 system and is not indicated for ophthalmic applications.

Prescription use √ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR *)! Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051541

4.3.1

Diagnostic Ultrasound Indications for Use Form

SSD-5000

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		See Below	
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)		P	P	P		P	P		See Below	
Intraoperative Neurological		P	P	P		P	P		See Below	
Pediatric		P	P	P		P	P		See Below	
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic		P	P	P		P	P		See Below	
Adult Cephalic		P	P	P		P	P		See Below	
Cardiac		P	P	P		P	P		See Below	
Transesophageal		P	P	P		P	P		See Below	
Transrectal		P	P	P		P	P		See Below	
Transvaginal		P	P	P		P	P		See Below	
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		See Below	
Laparoscopic		P	P	P		P	P		See Below	
Musculo-skeletal Conventional		P	P	P		P	P		See Below	
Musculo-skeletal Superficial		P	P	P		P	P		See Below	
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD. Intra-operative applications: include liver, pancreas and gall bladder. Small parts applications include breast. testes and thyroid.

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

Nancy C Brogdon Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) ~~Prescription~~ Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K051541

Diagnostic Ultrasound Indications for Use Form

GF-UE160-AL5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		See Below	
Intraoperative (specify)		N	N	N		N	N		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		N	N	N		N	N		See Below	Non-Cardiac
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.,

Intraoperative : Gastro-intestinal tract & surrounding abdominal organs

(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)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K051541