



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

Olympus America, Inc.
Laura Storms-Tyler
Director, Regulatory Affairs & Quality Assurance
Two Corporate Center Drive
Melville, NY 11747-3157

JUL 27 2015

Re: K011886
Trade/Device Name: Olympus EU-M60 EUS Exera Endoscopic Ultrasound Center
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODG, FET, IYO
Dated (Date on orig SE ltr): June 15, 2001
Received (Date on orig SE ltr): June 18, 2001

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of August 27, 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

**4.3.1 Indications for Use Form for
OLYMPUS EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER**

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 | | N | | | | | | | | |
| Transrectal | | N | | | | | | | | |
| Transvaginal | | N | | | | | | | | |
| Transurethral | | N | | | | | | | | |
| 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" :

- 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)

Nancy C. Brogdon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K011886

**4.3.2 Indications for Use Form for
EUS EXERA Ultrasonic Gastrovideoscope OLYMPUS GF TYPE UM160**

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 | | N | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) <small>NOTE</small> | | N | | | | | | | | |

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

Additional Comments:

Note1: Specification for "Other"

Gastrointestinal tract, biliary, pancreatic duct and surrounding 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 Brogan
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K011886

**4.3.3 Indications for Use Form for
OLYMPUS UM-DP12/20-35R Ultrasonic Probes**

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 | | N | | | | | | | | |
| Transrectal | | N | | | | | | | | |
| Transvaginal | | N | | | | | | | | |
| Transurethral | | N | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) <small>Note1</small> | | N | | | | | | | | |

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

Additional Comments:

Note 1: Specification for "Other" :

- Gastrointestinal tract, biliary, pancreatic duct and surround 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)

Nancy Brizon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K01886

**4.3.4 Indications for Use For
OLYMPUS UM-2R/3R Ultrasonic Probes**

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 | | P | | | | | | | | |
| Transrectal | | P | | | | | | | | |
| Transvaginal | | P | | | | | | | | |
| Transurethral | | P | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) ^{Note1} | | P | | | | | | | | |

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

Additional Comments:

Note1: 510(k) control numbers for the previously cleared indications
Gastrointestinal tract wall, biliary, pancreatic duct and surround organs. : K944610
Intraluminal ultrasound for upper airways and tracheobronchial tree: K982323
Urinary tract: K982610
Female reproductive tract: K001203
These previously control numbers were classified as the combination with the Olympus previous endoscopic ultrasound system EU-M30(K951994), EUS-20(K926514) and EU-M3(K882061).
The feature, efficiency, and acoustic output of UM-2R/3R are not changed when they are combined with the new system EU-M60.

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Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K011886

**4.3.5 Indications for Use for
OLYMPUS GF UM130 Ultrasound Gastrovideoscope**

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 | | | P | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) ^{Note1} | | | P | | | | | | | |

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

Additional Comments:

Note1: 510(k) control numbers for the previously cleared indications
Gastrointestinal wall, biliary, pancreatic duct, and surrounding organs: K971660
This previously control number was classified as the combination with the Olympus previous endoscopic ultrasound system EU-M30(K951994), EUS-20(K926514) and EU-M3(K882061). The feature, efficiency, and acoustic output of UM-2R/3R are not changed when they are combined with the new system EU-M60.

(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 Brogdon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 E1001 Number K011886

AUG 27 2001

K211886

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
of R & D Department 2951 Ishikawa-cho
Endoscope Division Hachioji-shi, Tokyo 192-8507
Japan
TEL 81-426-42-2891
FAX 81-426-46-5613

2. Initial Importer

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

3. Name of Contact Person

Name: Laura Storms-Tyler
Director, Regulatory affairs, Olympus America Inc.
Address, Phone and Fax: Two Corporate Center Drive
Melville, NY 11747-3157
TEL 516-844-5688
FAX 516-844-5416

B. Device Name, Common Name

1. Common/Usual Name

Diagnostic Ultrasound System with Accessories

2. Device Name

- OLYMPUS EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER
- EUS EXERA Ultrasonic Gastrovideoscope OLYMPUS GF TYPE UM160
- Ultrasonic Probes OLYMPUS UM-DP12/20-35R

3. Classification Name

| | FR Number | Product Code | Class |
|---------------------------------------|-----------|--------------|-------|
| Endoscope and accessories | 876.1500 | KOG | 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 |
|---|---------|
| Olympus EU-M30 Endoscopic Ultrasound Center | K951994 |

2. Ultrasonic Gastrovideoscope and Probes

| Device Name | #K |
|--|---------|
| Olympus GF TYPE UM130 Ultrasound Gastrovideoscope | K971660 |
| Olympus UM-2R/3R Ultrasonic Probes and associated ancillary equipment for GI | K944610 |
| Olympus UM-2R/ 3R Ultrasonic Probes and associated ancillary equipment (for bronchial use) | K982323 |
| Olympus UM-2R/3R Ultrasonic Probes and associated ancillary equipment (for urinary tract) | K982610 |
| Olympus UM-2R/3R Ultrasonic Probe and associated ancillary equipment (Ob/Gyn) | K001203 |

D. Device Description

1. Summary

The combination of OLYMPUS EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER, Ultrasonic Gastrovideoscope OLYMPUS GF TYPE UM160, and Ultrasonic probe OLYMPUS UM-DP12/20-35R makes an endoscopic ultrasound imaging system used to acquire and to display high-resolution and high-penetration, real-time ultrasound B-mode images.

2. Design

The EU-M60 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 the distal portion for MAJ-356RJ outer sheath of OLYMPUS UM-DP 12/20-35R Ultrasonic Probes 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-M60, as defined by FDA guidance documents, are:

| | |
|--|---------------|
| Transesophageal | Transrectal |
| Transvaginal | Transurethral |
| Other | |
| 1) Gastrointestinal tract, biliary, pancreatic duct and the surrounding Organs | |
| 2) Intraluminal ultrasound for upper airways and tracheobronchial tree | |
| 3) Urinary tract | |
| 4) Female reproductive tract | |

F. Technological Characteristics:

This device operates identically to the predicate devices in that the transducer of the endoscope or the ultrasonic probe 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.