K043275

DEC - 9 2004

## 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. GENERAL INFORMATION

**1. Applicant:** Olympus Medical Systems Corp.
(Former Name: Olympus Corporation) Hinode Plant
Address: 34-3 Hirai, Hinode-machi, Nishitama-gun
Tokyo, Japan, 190-0182
Establishment Registration No.: 3003637092

**2. Submission Correspondent:** Takashi Yagi
Olympus Medical Systems Corp.
(Former Name: Olympus Corporation)
Address: 2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507, Japan
Telephone: 81-426-42-2891
Facsimile: 81-426-42-3174
E-mail address: takashi_yagi@ot.olympus.co.jp
Establishment Registration No.: 8010047

3. Official Correspondent: Laura Storms-Tyler
Title: Director, Regulatory Affairs and Quality Assurance
OLYMPUS AMERICA INC.
Address: Two Corporate Center Drive, Melville, NY 11747-9058
Telephone: 631-844-5688
Facsimile: 631-844-5554
E-mail address: Laura.Storms-Tyler@olympus.com
Establishment Registration No.: 2429304

### 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

**3.Classification Name**

| | FR Number | Product Code | Class |
|---|---|---|---|
| Endoscope and accessories | 876.1500 | 78KOG | II |
| Ultrasonic pulsed echo imaging system | 892.1560 | 90IYO | II |

### C. Identification of the predicate or legally marketed device

The following devices information demonstrates that this device is considered substantially equivalent to a legally marketed, predicate medical device.

**1. Ultrasound System**

| Device Name | #K |
|---|---|
| OLYMPUS EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER | K011886 |
| ATL HDI 5000 Ultrasound System | K961459 |

## D. Device Description

### 1. Summary

The OLYMPUS EU-M60 EUS EXERA ENDOSCOPIC ULTRASOUND CENTER makes a endoscopic ultrasound imaging system used to acquire and to display high-resolution and high-penetration, real-time ultrasound B-mode 2D and 3D images.

### 2. Design

The EU-M60 is designed to comply with the standards listed below.

| | |
|---|---|
| IEC 60601-1 | 1988 : Amendment 1 (1992) and Amendment (1995) |
| IEC 60601-1-1 | 2000 |
| IEC 60601-1-2 | 1993 |
| IEC 60601-2-18 | 1996 |
| CISPR11 | 1990 |

## E. Intended Use:

The intended uses of the EU-M60, as defined by FDA guidance documents, are:

| | |
|---|---|
| Transesophageal | Transrectal |
| Transvaginal | Transurethral |
| Other<br>1) Gastrointestinal tract, biliary, pancreatic duct and the surrounding Organs<br>2) Intraluminal ultrasound for upper airways and tracheobronchial tree<br>3) Urinary tract<br>4) Female reproductive tract<br>5) 3D imaging | |

## 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2004

Olympus Medical Systems Corp.
% Mr. N. E. Devine, Jr.
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K043275
Trade Name: Olympus EU-M60 EUS EXERA Endoscopic Ultrasound Center
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Product Code: 78 KOG
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: November 23, 2004
Received: November 26, 2004

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 Olympus EU-M60 EUS EXTERA Endoscopic Ultrasound Center, as described in your premarket notification:

Transducer Model Number

| | |
|---|---|
| GF Type UM160 | UM-2R/3R |
| UM-DP12/20-35R | GF UM 130 |

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 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/dsma/dsmamain.html

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

Sincerely yours,

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

Enclosure(s)

## 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 | | P | | | | | | | | Note2(E) |
| Transrectal | | P | | | | | | | | Note2(E) |
| Transvaginal | | P | | | | | | | | Note2(E) |
| Transurethral | | P | | | | | | | | Note2(E) |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) Note1 | | P | | | | | | | | Note2(E) |

N= new indication; P= previously cleared by FDA in K011886; 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:

Note2:3D Imaging

(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)

David A. Seyerson

**(Division Sign-Off)**
**Division of Reproductive, Abdominal, and Radiological Devices**
**510(k) Number** K043275

## 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 | | P | | | | | | | | Note2(E) |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) Note1 | | P | | | | | | | | Note2(E) |

N= new indication; P= previously cleared by FDA in K011886; E= added under Appendix E

Additional Comments:
Note1: Specification for "Other"
Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.
Note2:3D Imaging

(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)

David A. Seguin

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and Radiological Devices
510(k) Number K043275

## 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 | | P | | | | | | | | Note2(E) |
| Transrectal | | P | | | | | | | | Note2(E) |
| Transvaginal | | P | | | | | | | | Note2(E) |
| Transurethral | | P | | | | | | | | Note2(E) |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) Note1 | | P | | | | | | | | Note2(E) |

N= new indication; P= previously cleared by FDA in K011886; E= added under Appendix E

Additional Comments:

Note1: Specification for "Other" :

Gastrointestinal tract, biliary, pancreatic duct and surround organs

Intraluminal ultrasound for upper airways and tracheobronchial tree

Urinary tract

Female reproductive tract:

Note2:3D Imaging

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

Prescription Use (Per 21 CFR 801.109)

David A. Hagan

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**Division of Reproductive, Abdominal, and Radiological Devices**
**510(k) Number** K043275

## 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 | | | | | | | | Note2(E) |
| Transrectal | | P | | | | | | | | Note2(E) |
| Transvaginal | | P | | | | | | | | Note2(E) |
| Transurethral | | P | | | | | | | | Note2(E) |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) Note1 | | P | | | | | | | | Note2(E) |

N= new indication; P= previously cleared by FDA in K011886; E= added under Appendix E

Additional Comments:

Note1: Specification for "Other" :

Gastrointestinal tract, biliary, pancreatic duct and surround organs

Intraluminal ultrasound for upper airways and tracheobronchial tree

Urinary tract

Female reproductive tract:

Note2:3D Imaging

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

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043275

## 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 | | | | | | | | Note2(E) |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) Note1 | | P | | | | | | | | Note2(E) |

N= new indication; P= previously cleared by FDA in K011886; E= added under Appendix E

Additional Comments:
Note1: Specification for "Other"
Gastrointestinal tract, biliary, pancreatic duct and surrounding organs.
Note2:3D Imaging

(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)

David A. Seymour

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Division of Reproductive, Abdominal,
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510(k) Number K043275