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

JUL 27 2015

Re: K022270
Trade/Device Name: Olympus Integrated Endosurgery System EndoALPHA (Control Unit for Endosurgery UCES-2), Models MAJ-1177, MA-2E and M-128/64/32/16/8PIE and PIU
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODA, GCJ, FAL, FCG, FEH, FWF, GEI, HIF, IYO, ITX and LFL
Dated (Date on orig SE ltr): July 12, 2002
Received (Date on orig SE ltr): July 15, 2002

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of August 14, 2002.

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

510(k) Number(if known): Not assigned yet K022270

Device Name:

OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES-2)

Indications for Use:

The "OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES-2)" has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, interlocking of the ancillary equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022270

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SMDA 510(k) SUMMARY

OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES-2)

A. Submitter's Name, Address, Phone and Fax Numbers

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjuku Monolis Nishi-Shinjuku, Shinjuku-ku Tokyo, Tokyo 163-0914 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-2891 FAX 81-426-46-5613

B. Name of Contact Person

Name:	Laura Storms-Tyler
Address, Phone and Fax Numbers:	Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name: #K981993 OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES-2)

Common Name: ENDOSURGERY SYSTEM

Classification:
21 CFR 876.1500 Endoscope and accessories
21 CFR 876.1075 Gastroenterology-urology biopsy instrument
21 CFR 876.4300 Endoscopic electrosurgical unit and accessories
21 CFR 878.4160 Surgical camera and accessories
21 CFR 878.4400 Electrosurgical cutting and coagulation device and accessories
21 CFR 884.1730 Laparoscopic insufflator
21 CFR 892.1560 Ultrasonic pulsed echo imaging system
21 CFR 892 1570 Diagnostic ultrasonic transducer
No Class (Ultrasonic Surgical Instrument)

Predicate Device: OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES) K981993

D. Description of the Device(s)

The "OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES-2)" has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, interlocking operation of the ancillary equipment.
The additional voice control function enables the subject device to control the ancillary equipment by voice, while the conventional products control them manually. You could find the details for voice commands and voice controllable equipment in "Standard set and ancillary equipment" and "Operation by voice control" of this section.

Addition of Image switching, recording and playback functions enables the followings:
- Images input into the UCES-2 and MAJ-1139 are displayed on two monitors by switching from one to another.
- Images input into the UCES-2 and MAJ-1139 are displayed on the MAJ-1176 as reference images.
- Still images input into UCES-2 and MAJ-1139 are recorded in a PC card (SmartMedia) .The images recorded in the PC card (SmartMedia) are displayed on the MAJ-1176.

The intended use of the EndoALPHA is to enable a central system to control various pieces of ancillary equipment. However, the approved indications for use for each separate ancillary device dictate the type of procedures that may be performed. This information is included in the instruction manual for each ancillary piece of equipment.

E. Intended Use of the Device(s)

The "OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES-2)" has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, interlocking operation of the ancillary equipment.
This is the same intended use as previously cleared one for the "OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA(CONTROL UNIT FOR ENDOSURGERY UCES)".

F. Summary including Conclusions drawn from Non-clinical Tests

The risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO14971-1. The design verification that were performed as a result of this risk analysis assessment are listed below. Refer to Attachment 3 for detail.

Modification	Test performed	Acceptance Criteria
Added the Voice Operation Function	1. Voice recognition test We confirmed the voice recognition rate by some sample voice data that is recorded by members of Olympus America Inc. 2. Wrong recognition test We confirmed whether EndoALPHA doesn't work by noise in operation room.	1. Recognize all words that is in specifications. 2. Never do wrong recognition.

ATTACHMENT

Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Product Code: 78 KOG, GCJ and FAL
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Product Code: 78 FCG
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Product Code: 78 FEH
Regulation Number: 21 CFR 878.4160
Regulation Name: Surgical camera and accessories
Product Code: 79 FWF
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Product Code: 79 GEI
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Product Code: 85 HIF
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: 90 IYO
Regulation Number: 21 CFR 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: 90 ITX
Regulation Number: Unclassified
Product Code: 90 LFL