



Food and Drug Administration
10903 New Hampshire Avenue
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Olympus Medical Systems Corp.
% Ms. Laura Storms-Tyler
Executive Director, RA & QA
Olympus America, Inc.
Two Corporate Center Drive
Melville, NY 11747-3157

JUL 27 2015

Re: K051613
Trade/Device Name: Olympus Integrated Endosurgery System EndoALPHA
(Control Unit for Endosurgery UCES-2) Software Version 3
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODA, GCI
Dated (Date on orig SE ltr): July 21, 2005
Received (Date on orig SE ltr): July 25, 2005

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of August 15, 2005.

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): 1051613

Device Name: Olympus Integrated Endosurgery System EndoALPHA

(Control Unit for Endosurgery UCES-2) Software Version 3

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, and interlocking operation of the ancillary equipment.

Prescription Use ~~AND/OR~~ Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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David A. Ferguson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number 1051613

AUG 16 2005

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510(k) SUMMARY

Olympus Integrated Endosurgery System EndoALPHA (Control Unit for Endosurgery UCES-2) Software Version 3

May 31, 2005

1 General Information

- Applicant
Olympus Medical Systems Corp.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
Establishment Registration No.: 8010047

- Official Correspondent
Laura Storms-Tyler
Executive Director,
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Establishment Registration No.: 2429304

- Manufacturer
Olympus Medical Systems Corp. Hinode Plant
34-3 Hirai Hinode-machi, Nishitama-gun,
Tokyo, Japan 190-0182
Establishment Registration No.: 3003637092

2 Device Identification

- Device Name
Olympus Integrated Endosurgery System EndoALPHA
(Control Unit for Endosurgery UCES-2) Software Version 3

- Common Name
Endosurgery System

- Regulation No:
21 CFR 876.1500

- Regulation Name:
Endoscope and accessories

- Regulatory Class:
II

- Product Code:
78 KOG

- Prescription Status:
Prescription device

- Performance Standards:
None established under Section 514 of FDCA.

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3 Predicate Device Information

- | | |
|------------------|---|
| ■ Device Name | Olympus Integrated Endosurgery System EndoALPHA
(Control Unit for Endosurgery UCES-2) Software Version 2 |
| ■ 510(k) No: | K041494 |
| ■ Decision Date: | 07/01/2004 |

4 Device Description

The Olympus Integrated Endosurgery System EndoALPHA (Control Unit for Endosurgery UCES-2) is the remote control unit of legally marketed ancillary equipment. The new clinical functions are not added to the ancillary equipment by the subject device. The subject device enables the remote control of the ancillary equipment, the display of their active states and the memory of the previous set-up values. The remote control is achieved by a touch-panel monitor, remote controller, and voice control. The voice control function enables the subject device to control the ancillary equipment by voice. The subject device does not come in contact with patients and is not subject to sterilization.

The only modifications that were made are:

- Add the operating function for the new ancillary equipment, Panasonic DVD recorder LQ-MD800.
- Enable the voice control of the ancillary equipment with the wireless microphone unit ew152G2 or Infrared Wireless Microphone System, in addition to the conventional wired microphone.
- Enable the control of the ancillary equipment with the ELO 15inch/19inch touch panel monitor 1526L/1926L, in addition to the conventional 12inch-touch panel monitor.
- Enable control of Audio Visual (AV) devices, Operating Room (OR) beds, and OR lights via the hospital's integrated audio-visual control system. The subject device sends commands for controlling these devices to the integrated audio-visual control system by remote control or voice control.
- Add a simplified main screen for the control panel monitor, in addition to the conventional GUI screen.

5 Intended Use

The Olympus Integrated Endosurgery System EndoALPHA (Control Unit for Endosurgery UCES-2) Software Version 3 has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, and interlocking operation of the ancillary equipment.

The intended use of the EndoALPHA as stated above 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.

This intended use is identical to the previously cleared one for the Olympus Integrated Endosurgery System EndoALPHA (Control Unit for Endosurgery UCES-2) Software Version 2.

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6 Conclusion

The risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2000. The design verifications that were performed as a result of this risk analysis assessment are described below.

Modification	Test performed	Acceptance criteria
Operating function for additional ancillary equipment	1.Nurse's control panel operation test: We confirmed whether the Nurse's control panel operation is performed correctly. 2.Surgeon's controller operation test: We confirmed whether the Surgeon's controller operation is performed correctly. 3.Voice operation test: We confirmed whether the voice operation is performed correctly.	1.All the operations that are in specification operate. 2.All the operations that are in specification operate. 3.All the operations that are in specification operate.

The Olympus Integrated Endosurgery System EndoALPHA (Control Unit for Endosurgery UCES-2) Software Version 3 has the following similarities to the predicate device:

- has the same intended use,
- uses the same operating principle.

In summary, the subject device described in this submission is, in our opinion, substantially equivalent to the predicate device.