AUG 16 2005

K051613

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, Regulatory Affairs & Quality Assurance Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-9058, USA Phone: 631-844-5688 FAX: 631-844-5554 Email:Laura.storms-tyler@olympus.com 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Olympus Medical Systems Corp.
c/o Ms. Laura Storms-Tyler
Executive Director, RA & QA
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

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: KOG and GCI
Dated: July 21, 2005
Received: July 25, 2005

Dear Ms. Storms-Tyler:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

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

Indications for Use

510(k) Number (if known): K051613

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)

David A. Lehman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051613