

JUL 01 2004

K041494

SMDA 510(k) SUMMARY

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This summary of 510(k) safety and effective information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR Section 807.93.

A. General Information

- 1. Applicant: Olympus Corporation
34-3 Hirai Hinode-machi
Nishitama-gun, Tokyo 190-0182, Japan
Registration No.: 3003637092
- 2. Initial Importer: Olympus America Inc.
Two Corporate Center Drive, Melville, NY 11747-3157
Registration No.: 2429304
- 3. Submission Correspondent: Tina Steffanie-Oak
Associate Manager, Regulatory Affairs/Clinical Monitor
Olympus America Inc.
Two Corporate Center Drive, Melville, NY 11747-3157
TEL: 631-844-5477
FAX: 631-844-5416
Registration No.: 2429304

B. Device Identification

- 1. Trade Name: OLYMPUS INTEGRATED ENDOSURGERY SYSTEM
EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES-2) Software Version 2
- 2. Common Name: ENDOSURGERY SYSTEM
- 3. Classification:

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

- 4. Class: Class II

C. Predicate Device Information

- 1. Trade Name: #K022270 OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES-2)
- 2. Common Name: ENDOSURGERY SYSTEM
- 3. Classification:

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

- 4. Class: Class II

D. Device Description

The "OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES-2) Software Version 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.

Addition of the operating function for ancillary equipment (UES-40, OTV-SP1C, LUS-2, DSR-45, UPA-P100MD and SonoSurg-IU) enables the following:

- The operating function for ancillary equipment operates the additional ancillary equipment (UES-40, OTV-SP1C, LUS-2, DSR-45, UPA-P100MD and SonoSurg-IU) by Nurse's control panel and voice control.

The voice control function enables the subject device to control the ancillary equipment by voice. You will find the details for voice commands and voice controllable equipment in "Standard set and ancillary equipment" and "Operation by voice control" in G. Device Description and Comparison.

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

The "OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDOSURGERY UCES-2) Software Version 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-2)".

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: 2000. The design verifications that were performed as a result of this risk analysis assessment are listed below. Refer to Attachment 3 for more details.

Modification	Test performed	Acceptance criteria
Voice operation function for additional ancillary equipment	<ol style="list-style-type: none">1. Voice recognition test We confirmed whether the voice recognition is performed correctly by some sample voice data.2. Wrong recognition test We confirmed whether EndoALPHA doesn't work by some noise in operation room.	<ol style="list-style-type: none">1. Recognize all words that are in specifications.2. Never do wrong recognition.
Operating function for additional ancillary equipment	<ol style="list-style-type: none">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 Nurse's control panel operation is performed correctly.	<ol style="list-style-type: none">1. All the operations that are in specification operate.2. All the operations that are in specification operate.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tina Steffanie-Oak
Associate Manager, Regulatory Affairs/Clinical Monitor
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K041494

Trade/Device Name: OLYMPUS INTEGRATED ENDOSURGERY SYSTEM EndoALPHA
(CONTROL UNIT FOR ENDOSURGERY UCES-2) Software Version 2
See Attachment 1

Regulation Number: 21 CFR §876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: II

Product Code: 78 KOG and GCJ

Dated: May 24, 2004

Received: June 4, 2004

Dear Ms. Steffanie-Oak:

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 (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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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>.

Sincerely yours,



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

Enclosure

ATTACHMENT 1

K041494 OLYMPUS ENDOALPHA INTEGRATED ENDOSURGCERY SYSTEM

Regulatory Class: II 21 CFR 876.1500; Procode: 78 KOG, GCJ,

- **UCES-2 Software Version 2,**
- **MAJ-1347 EndoALPHA system cable for UPA-P100MD**
- **MAJ-1175 Nurse's control panel for EndoALPHA**
- **MAJ-1176 Universal display for EndoALPHA**
- **MAJ-1140 Surgeon's controller for EndoALPHA**
- **MAJ-1141 System Interface cable for EndoALPHA**
- **MAJ-1142 I/F cable;**
- **MAJ-1143 EndoALPHA system cable for electro-surgical unit**
- **MAJ-1144 Surgeon's controller holder for EndoALPHA;**
- **MAJ-972 Long communication cable for boom mount EndoALPHA**
- **MAPC-10 PC card adapter**
- **M-XD512PIXD256P/128P/64P132P/16P: xD-Picture Card**
- **DSR-45 Sony Digital video recorder**

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

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Device Name: OLYMPUS INTEGRATED ENDSURGERY SYSTEM EndoALPHA

(CONTROL UNIT FOR ENDSURGERY UCES-2) Software Version 2

Indications for Use:

The "OLYMPUS INTEGRATED ENDSURGERY SYSTEM EndoALPHA (CONTROL UNIT FOR ENDSURGERY 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.

(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 G. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number

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