

AUG 21 1998

Page 1 of 3

510(k) SUMMARY *K 981993*
OLYMPUS INTEGRATED ENDOSCOPY SYSTEM EndoALPHA**A. Submitter's Name, Address, Phone and Fax Numbers****1. Manufacturer of the subject devices**

Name & Address of manufacturer: Olympus Optical Co., Ltd.
22-2 Nishi-Shinjuku, 1-Chome,
Shinjuku-ku, Tokyo 163-8610
Japan

Registration No.: 8010047

Address, Phone and Fax Numbers: 2951 Ishikawa-Cho,
of R&D Department, Hachioji-shi, Tokyo 192-8507
Endoscope Division Japan
TEL 0426-42-5101
FAX 0426-46-2786

B. Name of Contact Person

Name: Ms. Laura Storms-Tyler

Address, Phone and Fax Numbers: Olympus America Inc.
Endoscope Division
Two Corporate Center Drive
Melville, New York 11747-3157
TEL: (516) 844-5474
FAX: (516) 844-5416

C. Trade Name, Common Name, Classification Number, Classification Name and Predicate Devices

Trade Name: Olympus Integrated Endosurgery System
Endo ALPHA

Common Name: Control Unit for Endosurgery (UCES)

Classification Number
and Classification Name: 21CFR876.1500 Endoscope and accessories
21CFR876.4300 Endoscopic electrosurgical
unit and accessories

K981993
Page 2 of 3

MODEL	NAME	510(k) Number
UES-20	Electrosurgical Unit and its associated accessories	K970184
SonoSurg	SonoSurg System	K972114
UHI	UHI High Flow Insufflation Unit	K953163
CLV-S20	Subcutaneous Endoscopy System, OTV-S5C	K963184 K971416
OTV-SX	Subcutaneous Endoscopy System	K963184
IU-E1	Laparoscopic Ultrasound System	K944017
MB-631	Laparoscopic Ultrasound System	K944017
3DV	3D Surgical Endoscopy System	K943304 K943305 K943307
Crystal Eye E	3D Surgical Endoscopy System	K943304 K943305 K943307

E. Description of the Device

Olympus EndoAlpha Integrated Endoscopy System is the remote control unit of Olympus legally marketed ancillary equipment. No new clinical functions are added to the above ancillary equipment by the proposed device. This subject device enables the remote control of the ancillary equipment, the display of their action status and the memory of the previous set-up values.

F. Intended Use of the Device

Olympus EndoAlpha Integrated Endoscopy System has been designed to be used with Olympus endoscope ancillary equipment for central operation, central display, automatic initial setting and interlocking operation of the ancillary equipment.

G. Summary of the Technological Characteristics of the Device compared to the Predicate Devices

Olympus EndoAlpha Integrated Endoscopy System is the remote control unit of Olympus legally marketed ancillary equipment. No new clinical functions are added to the above ancillary equipment by the proposed device. Therefore, Olympus Endosurgery Integrated Endoscopy System does not affect safety of effectiveness when compared to the predicate devices.

K981993
Page 3 of 3

H. Summary including a Brief Discussion of Non-clinical Tests and How their Results support Determination of Safety & Efficacy

Design -

Olympus EndoAlpha Integrated Endoscopy System has been designed, manufactured and tested in compliance with Voluntary Safety Standards. It meets the requirements of IEC 60601-1 and IEC 60601-2, as well as CISPR 11.

Materials -

There are no new materials and patient-contacting materials.

I. Summary including Conclusions drawn from Non-Clinical Tests

When compared to the predicate devices, Olympus EndoAlpha Integrated Endoscopy System incorporates a significant change in the operating principle. However, no new clinical functions are added, and software validation has been conducted for the device relative to this change in operating principle. In terms of other issues of intended use, design and electrical safety, the subject device, EndoAlpha, does not incorporate any significant change that could affect the safety of effectiveness.

AUG 21 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Drive
Melville, NY 11042-1179Re: K981993
Olympus EndoALPHA Integrated Endosurgery System
Dated: June 4, 1998
Received: June 8, 1998
Regulatory Class: II
21 CFR 876.1500/Procode: 78 KOG, GCI, FAL
21 CFR 876.1075/Procode: 78 FCG
21 CFR 876.4300/Procode: 78 FEH
21 CFR 878.4400/Procode: 79 GEI
21 CFR 878.4160/Procode: 79 FWF
21 CFR 884.1730/Procode: 85 HIF
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX
Unclassified/Procode: 90 LFL

Dear Ms. Storms-Tyler:

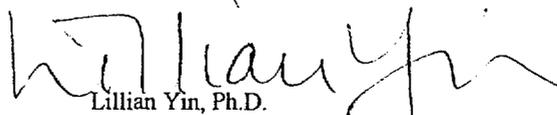
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 981993

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

Device Name: Olympus Integrated Endosurgery System EndoALPHA

Indications for Use:

The Olympus Integrated Endosurgery System EndoALPHA has been designed to be used with an Olympus endoscope ancillary equipment for central operation, central display, automatic initial setting and 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)

Peter R. Rathung
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use
(Per 21 CFR 801.109)

510(k) Number K981993 OR ~~Over The Counter Use~~