K030194

SMDA 510(k) SUMMARY

MAR 2 4 2003

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR Section 807.92.

A. General Information

Applicant:	OLYMPUS OPTICAL CO.LTD.
Address:	34-4 Hirai Hinode-machi, Nishitama-gun, Tokyo, Japan 190-0182
Establishment Registration No.:	3003637092
Submission Correspondent:	Mayumi Ishii OLYMPUS OPTICAL CO., LTD.
Address:	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507, Japan
Telephone:	81-426-42-2891
Facsimile:	81-426-42-2291
E-mail address:	ma_ishii@ot.olympus.co.jp
Establishment Registration No.:	8010047
Official Correspondent:	Laura Storms-Tyler
Title:	Director, Regulatory Affairs/Quality Assurance OLYMPUS AMERICA INC.
Address:	Two Corporate Center Drive, Melville, NY 11747-3157
Telephone:	631-844-5688
Facsimile:	631-844-5416
E-mail address:	Laura.Storms-Tyler@olympus.com
Establishment Registration No.:	2429304

B. Device Identification

Device Name:	XUES-41
Common/Usual Name:	Electrosurgical Unit and its associated accessories
Class:	II
CFR Classification Number:	21CFR 876.4300
Classification Panel:	Gastroenterology & Urology
Product Code:	78-KNS
514 Performance Standard:	Not established

C. Predicate Devices:

Model	Device Description & 510(k)#/ Date Cleared	Manufacturer
OLYMPUS UES-30 ELECTROSURGICAL UNIT	#K023767 NOV/29/1997	Olympus Optical Co., Ltd.
GYRUS Endourology System	#K990628 JUN/29/1999	Gyrus Medical Ltd.

D. Description of the Device

Standard Set

The standard set of the XUES-41 Electrosurgical Unit includes the following components:

MODEL NAME	DEVICE DESCRIPTION	510(K)#
XUES-41	Electrosurgical Unit	Part of this submission
Foot switch	Foot switch for Electrosurgical Unit	Part of this submission
Power cord	Power cord	#K911904

a) XUES-41 Electrosurgical Unit

The Electrosurgical Unit XUES-41 produces the high frequency current waveform delivered to tissue via the electrosurgical accessories and electrodes. When the high frequency current is fed through tissue, it generates heat rises, causing changes from protein degeneration to desiccation and vaporization.

b) Footswitch

The Footswitch is designed to connect to the XUES-41 unit. It offers handsfree control of the ON/OFF function during the procedure.

Recommended Accessories

The following associated accessories are designed and recommended with the XUES-41 Electrosurgical Unit.

MODEL NAME	DEVICE DESCRIPTION	510(K)#
NA	A-Cord	K970184
MAJ-619	A-Adapter	K970184
NA	Bipolar Electrodes	K970184
S1518/1	Working Element, Passive	Part of this submission
S1518/2	Working Element, Active	Part of this submission
S1518/3	HF Resection Electrode	Part of this submission
S1518/4	HF-cable	Part of this submission

a) S1518-1/2/3/4

The S1518-1/2/3/4 are to be combined together and make up a high frequency therapeutic device. The S1518-1/2 are handle parts; the S1518-1's movement is passive and the S1518-2's active. The S1518-3 consists of a cutting loop and stabilizing tube and it performs coagulation and cutting at the cutting loop by applying high frequency current. The S1518-4 is a HF cable to connect the XUES-41 and the combination of the S1518-1/2/3. The S1518-1/2/4 are reusable, while the S1518-3 is sterile, single use.

E. Intended Use of the device

This instrument has been designed for use in a medical facility under the supervision of a trained physician. It has been designed for general(open) and endoscopic surgery including urology, gynecology, respiratory and gastroenterology in conjunction with Olympus designed electrosurgical accessories, endoscopes(fiberscopes, videoscopes and rigid scopes)

applicable for electrosurgery(cutting and coagulation), light sources and other ancillary equipment.

F. Reason for Not Requiring Clinical Data

The subject XUES-41 is similar to the OLYMPUS UES-30 Electrosurgical UNIT cleared in the previous 510(k) #K023767, Gyrus cleared in the previous 510(k) #990628. And when compared to the predicated devices listed above, the Olympus XUES-41 Electrosurgical UNIT does not incorporate any significant change in intended use, method of operation, material, or design that could affect safety and effectiveness. Therefore the clinical data is not necessary for its evaluation of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2003

Olympus Optical Co., Ltd.
c/o Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K030194
Trade/Device Name: XUES-41 Endoscopic Electrosurgical Unit
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: 78 KNS
Dated: March 17, 2003
Received: March 19, 2003

Dear Mr. Sherratt:

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 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:

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" (21 CFR Part 807.97). 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

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

Enclosure

510(k) Number(if known): K030194

Device Name: XUES-41 Electrosurgical Unit and its associated accessories

Indications for Use:

This instrument has been designed for use in a medical facility under the supervision of a trained physician. It has been designed for general(open) and endoscopic surgery including urology, gynecology, respiratory and gastroenterology in conjunction with Olympus designed electrosurgical accessories, endoscopes(fiberscopes, videoscopes and rigid scopes) applicable for electrosurgery(cutting and coagulation), light sources and other 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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030194