K 032066

OCT - 3 2003

SMDA 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. GENERAL INFORMATION

1. Applicant

Name & Address:	Aomori Olympus Co., Ltd. 2-248-1 Okkonoki Kuroishi-shi, Aomori-ken, Japan 036-0357
Registration Number:	9614641

2. Initial Importer

Name & Address:	Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-3157
Registration Number:	2429304

3. Submission Correspondence

Name, Address, Tel & Fax, Contact:	Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-3157 TEL 631-844-5477 FAX 631-844-5416 Tina Steffanie-Oak, Senior RA Analyst
Registration Number:	2429304

B. DEVICE IDENTIFICATION

1. Common/Usual Name
Surgical System

2. Device Name
Olympus SonoSurg System

3. Classification Name

CFR Number	Classification Name	Class	Product Code
Not established	Ultrasonic Surgical Instrument	II	LFL

C. IDENTIFICATION OF LEGALLY MARKETED DEVICES WHICH WE CLAIM SUBSTANTIAL EQUIVALENCE

Model	510(k)#	Manufacturer	Class	Product Code
Olympus Ultrasonic Surgical System	#K021962	Olympus	II	LFL
CUSA Excel Ultrasonic Surgical Aspirator System	#K981262	Valleylab	II	LFL
SONOPET UST-2001 Ultra Surgical Aspirator	#K010309	Miwatec	II	LFL
Ultrasonic Surgical System	#K962952	Olympus Optical Co., Ltd.	II	LBK

Please see abbreviated comparison table of SonoSurg System and Predicate Devices.

D. DEVICE DESCRIPTION

1. Summary

In conclusion, the subject device is substantially equivalent to the predicate devices. A comparison table of the subject device and predicate devices is found in Attachment 2-A.

2. Design

The Olympus SonoSurg System has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC 60601-1, IEC 60601-1-1 and IEC 60601-2-2.

3. Materials

All the patient contacting materials used in this system are identical materials that have been cleared in the past 510(k) submissions. All materials have been confirmed with ISO 10993-1.

3. Intended Use of the device

The Olympus SonoSurg System consists of the SonoSurg Generator (SonoSurg-G2 Set), SonoSurg Irrigation Unit (SonoSurg-IU), SonoSurg Transducers (SonoSurg-T2L-GE, SonoSurg-T2L-GE-C), and SonoSurg ultrasonic surgical instruments and surgical suction devices (T3000 Series). This system is intended to dissect, fragment, emulsify, and aspirate tissue for General Surgery, Laparoscopic Surgery, Plastic and Reconstructive Surgery, and Urological Surgery. This system may also be combined with electrosurgery using Olympus Model UES-20 or UES-30 Electrosurgical Units.

5. Summary including conclusion drawn from Non-clinical Tests

When compared to the Olympus Ultrasonic Surgical System(#K021962), CUSA EXcel Ultrasonic Surgical Aspirator System(#K981262), SONOPET UST-2001 Ultra Surgical Aspirator(#K010309) and Ultrasonic Surgical System(#K962952), the Olympus Surgical System does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect safety and effectiveness. Therefore 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

OCT - 3 2003

The Olympus Optical Company
c/o Ms. Tina Steffanie-Oak
Associate Manager, Regulatory Affairs/Clinical Monitor
Olympus America, Inc.
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K032066
Trade/Device Name: Olympus SonoSurg System
Regulatory Class: Unclassified
Product Code: LFL
Dated: July 3, 2003
Received: July 7, 2003

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 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 (301) 594-4659. 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 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,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

OLYMPUS

Indications for Use Statement

510(k) Number (if known): K032066

Device Name: Olympus SonoSurg System

Indications for Use :

The Olympus SonoSurg System consists of the SonoSurg Generator (SonoSurg-G2 Set), SonoSurg Irrigation Unit (SonoSurg-IU), SonoSurg Transducers (SonoSurg-T2L-GE, SonoSurg-T2L-GE-C), and SonoSurg ultrasonic surgical instruments and surgical suction devices (T3000 Series). This system is intended to dissect, fragment, emulsify, and aspirate tissue for General Surgery, Laparoscopic Surgery, Plastic and Reconstructive Surgery, and Urological Surgery. This system may also be combined with electrosurgery using Olympus Model UES-20 or UES-30 Electrosurgical Units.

(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

(Prescription 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhern

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

510(k) Number K032066