K041566

SEP - 8 2004

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 Correspondent

Name, Address, Tel & Fax:	OLYMPUS AMERICA Inc. Two Corporate Center Drive, Melville, NY 11747-3157 Tina Steffanie-Oak Associate Manager, Regulatory Affairs/Clinical Monitor 631-844-5477 631-844-5416
Registration Number:	2429304

B. DEVICE IDENTIFICATION

1. Common/Usual Name
Ultrasonic Surgical System

2. Device Name
SonoSurg Ultrasonic Surgical System

3. Class, Classification Number and Classification Name
No classification, Ultrasonic Surgical Instrument, 80LFL

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

The following list identifies the predicate devices:

Model	510(k)#	Manufacturer	Class	Product Code
SonoSurg System	#K032066	Olympus Corporation	No Classification	80-LFL
SonoSurg Trocar XT3900 System	#K000095	Olympus Corporation	II	80-LFL
Ultrasonic Surgical System	#K021962 #K031710 #K031523 #K031305	Olympus Corporation	No Classification	80-LFL
CUSA Excel Ultrasonic Surgical Aspirator System	#K981262	Valleylab	No Classification	80-LFL 84-LBK
SONOPET UST-2001 Ultra Surgical Aspirator	#K010309	Miwatec	No Classification	80-LFL
Ultrasonic Surgical System USU	#K962952	Olympus Corporation	No Classification	84-LBK

D. DEVICE DESCRIPTION

1. Summary

The subject SonoSurg is an ultrasonic surgical device designed to be used with Generator, Irrigation Unit and Transducer and ultrasonic surgical instruments to dissect, fragment, emulsify and aspirate tissue in the neurosurgical field. This system consists of the SonoSurg Generator (SonoSurg-G2 set), SonoSurg Irrigation Unit (SonoSurg-IU), SonoSurg Transducer(SonoSurg-T2L-MS), and SonoSurg ultrasonic surgical instruments, and is designed to be used with a separate surgical suction source.

2. Design

This 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 60601-1-2.

3. Materials

Certificate of Identical Materials is included in Attachment 5. Concerning the patient contacting part, some materials are identical with the predicate device. While the others are not identical with the predicate device, biocompatibility testing was performed in accordance with ISO 10993-1. The test data has shown in Attachment 5-A.

4. Intended Use of the device: Indications for Use of the SonoSurg Ultrasonic Surgical System

The SonoSurg Ultrasonic Surgical System is indicated for use in surgical procedures in neurosurgery where dissection, fragmentation, emulsification and aspiration of soft tissue are desirable.

This system consists of the SonoSurg Generator (SonoSurg-G2 set), SonoSurg Irrigation Unit (SonoSurg-IU), SonoSurg Transducer (SonoSurg-T2L-MS), and SonoSurg ultrasonic surgical instruments, and is designed to be used with a separate surgical suction source. Do not use this system for any purpose other than its intended use.

5. Summary including conclusion drawn from Non-clinical Tests

When compared to the Olympus SonoSurg System (#K032066), CUSA EXcel Ultrasonic Surgical Aspirator System (#K981262), SONOPET UST-2001 Ultra Surgical Aspirator (#K010309) and Ultrasonic Surgical System (#K962952, #K000095, #K021962, #K031710,

#K031523, #K031305), SonoSurg Ultrasonic Surgical System does not incorporate any significant changes in the intended use, method of operation, material, or design that could affect safety or 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

SEP - 8 2004

Aomori Olympus Co., Ltd.
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: K041566
Trade/Device Name: SonoSurg Ultrasonic Surgical System
Regulatory Class: Unclassified
Product Code: LFL
Dated: June 8, 2004
Received: June 10, 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.

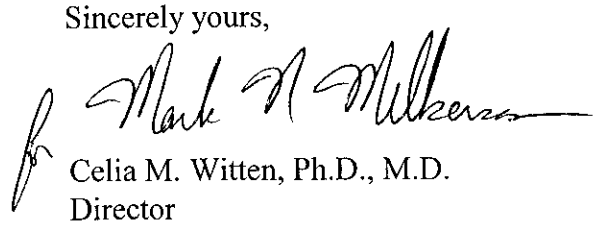
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

510(k) Number (if known): K041566

Device Name: SonoSurg Ultrasonic Surgical System

Indications for Use:

Indications for Use of SonoSurg Ultrasonic Surgical System

The SonoSurg Olympus Ultrasonic Surgical System is indicated for use in surgical procedure in neurosurgery where dissection, fragmentation, emulsification and aspiration of soft tissue are desirable.

This system consists of the SonoSurg Generator (SonoSurg-G2 set), SonoSurg Irrigation Unit (SonoSurg-IU), SonoSurg Transducer (SonoSurg-T2L-MS), and SonoSurg ultrasonic surgical instruments, and is designed to be used with a separate surgical suction source.

Do not use this system for any purpose other than its intended use.

(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)

for Mark N Milhem

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K041566