JAN 2 5 2005

K 042160

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 11747-9058
Registration Number:	2429304

3. Submission Correspondence

Name, Address, Tel & Fax:	Tina Steffanie-Oak Associate Manager, Regulatory Affairs/Clinical Monitor Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-9058 TEL 631-844-5477 FAX 631-844-5554
Registration Number:	2429304

B. DEVICE IDENTIFICATION

1. Common/Usual Name
Ultrasonic Surgical Instrument

2. Device Name
SonoSurg Trocar

3. Classification Name
No classification, class II , LFL

C. PREDICATE DEVICES

Device Name	510(k) #	Manufacturer	Class	Product Code
SonoSurg Trocar XT3900	#K000095	Olympus Corporation.	No Classification	LFL
Olympus SonoSurg System	#K021962 #K031305 #K031523 #K031710	Olympus Corporation	No Classification	LFL

D. SUMMARY DESCRIPTION OF THE DEVICE

1. Summary

The SonoSurg Trocar is an Ultrasonic trocar for endoscopic surgery which enable the puncture and cutting of the abdominal wall with tissue coagulation by means of ultrasonic vibration. SonoSurg Trocar is composed of two sections, the SonoSurg Trocar and the Olympus SonoSurg Generator SonoSurg-G2.

The SonoSurg Trocar is composed of a trocar transducer, dilator, valve, trocar tube, insertion sheath, probe, and Olympus SonoSurg Generator SonoSurg-G2, which provides ultrasonic vibration to the SonoSurg Trocar.

2. Design

The Olympus SonoSurg Generator SonoSurg-G2 has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC 60601-1: 1995, IEC 60601-1-1:2000 and IEC 60601-2-18:1996, Amendment:2000.

3. Materials

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

E. INTENDED USE OF THE DEVICE

SonoSurg Trocar

These instruments have been designed to be used with the SonoSurg generator (SonoSurg-G2) to be inserted into the body cavity wall by means of ultrasonic waves under endoscopic surgery in order to coagulate and cut living tissue as well as to place a trocar tube on the body cavity wall.

SonoSurg -G-2

This instrument has been designed to be used with the SonoSurg transducers and the SonoSurg ultrasonic surgical instruments to cut and coagulate soft tissue for laparoscopic and general (open) surgery in intraabdominal and obsteric/gynecologic procedure, and endoscopic and, general surgery in ENT (Ears, Nose, Throat), thoracic, and urologic procedures.

This instrument may also be combined with SonoSurg Irrigation unit (SonoSurg-IU). Please refer to the SonoSurg-IU instruction manual to review the intended use of this combined system.

This instrument may be combined with SonoSurg Trocar. Please refer to the SonoSurg Trocar instruction manual to review the intended use of this combined system.

F. TECHNOLOGICAL CHARACTERISTICS

Theory of the operation of SonoSurg Trocar is that the electrical energy employed in the generator is changed to mechanical energy by ultrasonic vibration in the hand piece. System can cut and coagulate body tissue by ultrasonic vibration. This system is equivalent the predicate device, the Olympus SonoSurg System SonoSurg-G2(#K000095).

G. REASON FOR NOT REQUIRING CLINICAL DATA

When compared to the predicate device, the SonoSurg Trocar does not incorporate any significant change that impacts safety and efficacy in comparison to the predicate device. Therefore, clinical data is not necessary to establish the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2005

Aomori Olympus Co.,Ltd.
c/o Ms. Laura Storms-Tyler
Executive Director, RA/QA
Olympus America, Inc.
Two Corporate Center Drive
Melville, New York 11747

Re: K042160
Trade/Device Name: SonoSurg Trocar
Regulatory Class: Unclassified
Product Code: LFL
Dated: December 22, 2004
Received: December 30, 2004

Dear Ms. Storms-Tyler:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

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

510(k) Number (if known): K 042160

Device Name: SonoSurg Trocar

Indications for Use:

1) Indications for Use of SonoSurg Trocar

This instrument has been designed to be used with the SonoSurg generator (SonoSurg-G2) and is inserted into the body cavity wall by means of ultrasonic waves under endoscopic surgery in order to coagulate and cut soft tissue as well as to place a trocar tube within the body cavity wall.

2) Indications for Use of SonoSurg G-2 Set

This instrument has been designed to be used with the SonoSurg transducers and the SonoSurg ultrasonic surgical instruments for soft tissue cutting and coagulation for laparoscopic and general (open) surgery in intraabdominal and obstetric/gynecologic procedures, and endoscopic and general surgery in ENT (Ears, Nose, Throat), thoracic, and urologic procedures.

This instrument may also be combined with the SonoSurg Irrigation Unit (SonoSurg-IU). Please refer to the SonoSurg-IU instruction manual to review the intended use of this combined system.

This instrument may also be combined with the SonoSurg Trocar. Please refer to the SonoSurg Trocar instruction manual to review the intended use of this combined system.

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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042160