K 050885

JUN 3 - 2005

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: OLYMPUS MEDICAL SYSTEMS Corp.
Address: 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
Establishment Registration No.:8010047

2. Manufacturer: Aomori Olympus Co., Ltd.
Address: 248-1 Okkonoki 2-chome Kuroishi-shi Aomori, Japan, 036-0367
Establishment Registration No.:9614641

3. Submission Correspondent: OLYMPUS AMERICA Inc.
Address: Two Corporate Center Drive, Melville, NY 11747-3157
Contact: Laura Storms-Tyler
Title: Director, Regulatory Affairs and Quality Assurance
Telephone: 631-844-5688
Facsimile: 631-844-5554
E-mail address: Laura.Storms-Tyler@olympus.com
Establishment Registration No.:2429304

4. Initial Importer: OLYMPUS AMERICA Inc.
Address: Two Corporate Center Drive, Melville, NY 11747-3157
Establishment Registration No.:2429304

B. DEVICE IDENTIFICATION

1. Common/Usual Name
Ultrasonic Surgical Instrument

2. Device Name
Olympus Ultrasonic Surgical System SonoSurg

3. Classification Name
Class II , LFL – Instrument, Ultrasonic Surgical

C. PREDICATE DEVICES

Device Name	510(k) #	Manufacturer	Class	Product Code
Olympus Ultrasonic Surgical System	#K021962 #K031523 #K031710	Olympus Corporation	II	LFL
Olympus SonoSurg System	#K972114	Olympus Corporation.	II	LFL

D. SUMMARY DESCRIPTION OF THE DEVICE

1. Summary

The major components of this system are the generator, handpiece, and accessories. The generator supplies electrical energy for ultrasonic vibration of the handpiece (transducer). The ultrasonic vibration is transferred to the tip of probe. Soft body tissue is incised and coagulated through the ultrasonic energy delivered by the handpiece.

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

All of the patient contacting materials used in the components of the "Olympus Ultrasonic Surgical System SonoSurg" are identical materials used in legally marketed Olympus devices.

E. INTENDED USE

These instruments (ultrasonic surgical instruments, ultrasonic generator, and transducers) have been designed to be used together to cut and coagulate soft tissue in bariatric procedures which include: laparoscopic and general (open) surgery in intraabdominal, obstetric/gynecologic, thoracic and urologic procedures. The ultrasonic surgical instruments are also compatible for use with an electrosurgical unit.

F. TECHNOLOGICAL CHARACTERISTICS

The mechanism of this system is that the electrical energy employed in the main unit is changed to mechanical energy by ultrasonic vibration. This is the same as the referenced Olympus predicate devices.

G. REASON FOR NOT REQUIRING CLINICAL DATA

When compared to the predicate device, the Ultrasonic Surgical System SonoSurg 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

JUN 3 - 2005

Olympus Medical Systems Corporation
C/o Ms. Laura Storms-Tyler
Director, Regulatory Affairs and Quality Assurance
Olympus America Incorporated
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K050885
Trade/Device Name: Olympus Ultrasonic Surgical System SonoSurg
Regulatory Class: Unclassified
Product Code: LFL
Dated: March 17, 2005
Received: April 7, 2005

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

Enclosure

510(k) Number(if known): ~~Not assigned yet~~ K 050885

Device Name: Olympus Ultrasonic Surgical System SonoSurg

Indications for Use:

These instruments (ultrasonic surgical instruments, ultrasonic generator, and transducers) have been designed to be used together to cut and coagulate soft tissue in bariatric procedures which include: laparoscopic and general (open) surgery in intraabdominal, obstetric/gynecologic, thoracic and urologic procedures. The ultrasonic surgical instruments are also compatible for use with an electrosurgical unit

(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 General, Restorative
and Neurological Devices
K050885