

MAY 18 1998

K972114

OLYMPUS

**510(k) Summary
Olympus SonoSurg System**

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

510(k) number : Not assigned yet

Device Name: Olympus SonoSurg System

Common/Usual Name: Ultrasonic surgical system

Classification Name: No classification

Predicate Devices:	Harmonic Scalpel Generator	Utracision	K#905315
	Ultrasonic Surgical System USU	Olympus	K#962952
	Harmonic Scalpel Laparoscopic	Utracision	K#925699
	Clamp Coagulator		
	HIQ Hand Instruments	Olympus	K#944201

Prepared by: Mr. Yoshihito Shimizu
Manager, Product Development Department, Endoscope Division
Olympus Optical Co., Ltd.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan

Summary Preparation Date: May 7, 1997

Statement of intended use:

The Olympus SonoSurg System has been for use in medical facilities under supervision of a trained physician. This system designed to incise and coagulate body tissues for general, laparoscopic, and intera abdominal surgery. The operation of SonoSurg System is that the electrical energy employed in the main unit is exchanged mechanical energy by ultrasonic vibration in the handpiece.

Therefore, This system can incise, and coagulate body tissue by ultrasonic vibration.

Device description:

The major components of this system are Generator, Handpiece, and accessories. This SonoSurg generator is supplied the electrical energy to transducer built-in handpiece. The electrical energy is exchanged mechanical energy by ultrasonic vibration at the transducer. The ultrasonic vibration is transferred to the tip of probe. In conjunction with the Generator, the body tissue is incised and coagulated with handpiece.

Predicate devices for this system are following:

Harmonic Scalpel Generator	Utracision	K#905315
Ultrasonic Surgical System USU	Olympus	K#962952
Harmonic Scalpel Laparoscopic	Utracision	K#925699
Clamp Coagulator		
HIQ Hand Instruments	Olympus	K#944201

Actuation mechanism of the USU and the LCS is the same as the SonoSurg System based as the following:

The ultrasonic vibrating which is generated in this system is transferred to the probe, is mounted on the edge of a handpiece.

Both the SonoSurg System and the USU use the ultrasonic and operate with the almost same frequency. However, the USU incises the soft tissue by use of the shock force of ultrasound. The SonoSurg System is safer than the USU.

General safety and conclusions:

The Olympus SonoSurg System is designed, manufactured and tested in compliance with Voluntary Safety Standards. It meets the requirements of IEC 601-1 and IEC 601-1-2, as well as CISPR 11.

When compared to the predicate devices, the Olympus SonoSurg System does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1998

Ms. Susan D. Goldstein-Falk
Official Correspondent for
Olympus Optical Company, Limited
c/o MDI Consultants, Incorporated
55 Northern Boulevard
Great Neck, New York 11021

Re: K972114
Trade Name: Olympus SonoSurg System
Regulatory Class: II
Product Code: LFL
Dated: February 13, 1998
Received: February 17, 1998

Dear Ms. Goldstein-Falk:

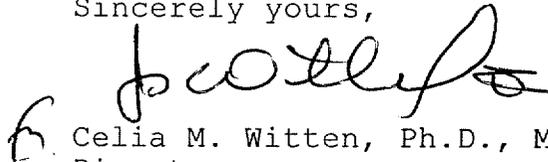
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

510(k) Number # 972114

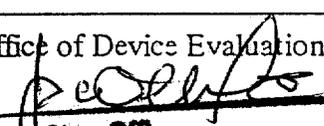
Device Name: Olympus SonoSurg System

Indication for use:

This system is designed to incise and coagulate soft tissue for laparoscopic and intraabdominal procedures in general surgery.

(Please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 972114

Prescription Use
(Per 21 CFR 801.109)

or

Over-The-Counter Use
(Optional Format 1-2-96)