AUG 12 1999

Sound Surgical Technologies LLC

Creating the Perfect Wave

1300 Plaza Court North, Suite 203, Lafayette, CO 80026 tel 303.926.8608 fax 303.926.8615
SSTmail@soundsurgical.com

510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K991791

Submitter

Sound Surgical Technologies LLC
1300 Plaza Court North, #203
Lafayette, Colorado 80026

Contact Person

William W. Cimino, Ph.D. 303-926-8608 (TEL)
303-926-8615 (FAX)

Date Prepared

May 24, 1999

Proprietary Name

SoundVASER System

Common, Usual, or Classification Name

Instrument, Ultrasonic Surgical

Classification

Class: Class II
Panel: 21 CFR 878, General and Plastic Surgery
Product Code: LFL

Predicate Devices

The SoundVASER System is similar in technical design and operation to other surgical systems with ultrasonic vibration, irrigation, and suction that the FDA has determined to be substantially equivalent to pre-amendment devices as depicted below:

- Valleylab Inc., CUSA Excel Ultrasonic Surgical Aspirator System (K981262) and CUSA Lap Accessory (K921251)

Device Description

The SoundVASER System is comprised of an ultrasonic generator (110/120 and 220/240 VAC, 50 & 60 Hz), an ultrasonic surgical handpiece with an ultrasonic surgical probe, and a suction/irrigation subsystem. The ultrasonic surgical handpiece converts electrical energy supplied by the ultrasonic generator into vibratory motion. The vibratory motion is applied to the ultrasonic surgical probe that is attached to the ultrasonic surgical handpiece. The vibratory motion at the tip of the ultrasonic surgical probe fragments and emulsifies contacted soft tissues. The suction/irrigation subsystem is used to remove the fragmented tissues. The suction and irrigation functions may be performed simultaneously or independently.

Intended Use

The SoundVASER System is indicated for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired: Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, and Laparoscopic Surgery.

Summary of Technological Characteristics

The SoundVASER System is similar with regard to design, operation, materials, methods of sterilization, and intended use to the predicate devices indicated above. Therefore, no new safety or efficacy issues are created and the SoundVASER System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

William W. Cimino, Ph.D.
President
Sound Surgical Technologies LLC
1300 Plaza Court North, Suite 203
Lafayette, Colorado 80026

Re: K991791
Trade Name: Sound Vaser System
Regulatory Class: II
Product Code: LFL
Dated: May 24, 1999
Received: May 26, 1999

Dear Dr. Cimino:

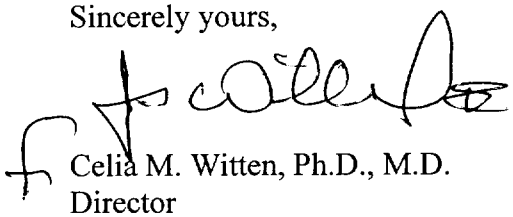
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (if known): K991791

Device Name: SoundVASER System

Indications for Use:

The SoundVaser System is indicated for use in the following surgical specialties when the fragmentation, emulsification, and aspiration of soft tissue is desired:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic 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 K991791

Prescription Use ✓ OR Over-The-Counter Use ___
(per 2.1 CFR 801.109)
(Optional Format 1-2-96)