DEC 21 1999

***Sound Surgical Technologies LLC***

**Creating the Perfect Wave**

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# 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: K993868

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

November 10, 1999

Proprietary Name

SoundVASER Dissection System

Common, Usual, or Classification Name

Instrument, Ultrasonic Surgical

Classification

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

K993868

Predicate Devices

The SoundVASER Dissection System is similar in technical design and operation to other surgical systems that utilize ultrasonic frequency vibrating instruments for soft tissue cutting and coagulation that the FDA has determined to be substantially equivalent to pre-amendment devices as depicted below:

Ethicon Endo-Surgery, Cincinnati, OH USA

- Ultracision Harmonic Scalpel Handpiece, K990430, LFL
- Ultracision 5mm Instruments, K983316, LFL
- Ultracision 5mm Laparosonic Hook Blades, K971302, LFL
- Ultracision 5mm Hard Sheath LaparoSonic Blade, K962584, LFL

Device Description

The SoundVASER Dissection System is comprised of an ultrasonic surgical handpiece and associated dissection tips. The ultrasonic surgical handpiece converts electrical energy supplied by the SoundVASER ultrasonic generator into vibratory motion. The vibratory motion is applied to the dissection tip that is attached to the ultrasonic surgical handpiece. The vibratory motion at the tip cuts and coagulates contacted soft tissues.

Intended Use

The SoundVASER Dissection System (dissection tips and handpiece for The SoundVaser System) is indicated for use in when cutting and coagulation of soft tissues is desired, including bleeding control with minimal thermal damage.

Summary of Technological Characteristics

The SoundVASER Dissection 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 Dissection 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

DEC 21 1999

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

Re: K993868
Trade Name: SoundVASER Dissection System
Regulatory Class: II
Product Code: LFL
Dated: November 12, 1999
Received: November 15, 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,

for 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): K993868

Device Name: The SoundVASER Dissection System
(Dissection Tips and Handpiece for The SoundVASER System)

**Indications for Use:**

The SoundVASER Dissection System (Dissection Tips and Handpiece for The SoundVaser System) is indicated for use in when cutting and coagulation of soft tissues is desired, including bleeding control with minimal thermal injury.

(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 K993868

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