Sound Surgical Technologies LLC.
Stephen Smith
Vice President Of RA / Qa
357 S. Mccaslin Blvd. #100
Louisville, Colorado 80027

June 9, 2021

Re: K110306
Trade/Device Name: Sound Surgical Vaser 2.1 Lipo System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Stephen Smith:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 23, 2011. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sound Surgical Technologies, LLC
% Mr. Stephen C. Smith
VP of RAQA
357 McCaslin Boulevard, Suite 100
Louisville, Colorado 80027

JUN 23 2011

Re: K110306
Trade/Device Name: Sound Surgical Technologies LLC VASER 2.1 Lip System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: June 20, 2011
Received: June 21, 2011

Dear Mr. Smith:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110306

Device Name: Sound Surgical Technologies LLC VASER 2.1 Lipo System

Indications for Use:

The Sound Surgical VASER 2.1 is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.

The Sound Surgical VentX 2.1 is intended for the suction or aspiration of fluids and tissue during surgical procedures. The VentX 2.1 is designed to operate with the Sound Surgical VASER 2.1 or as a stand-alone system.

The Sound Surgical VASER 2.1 Lipo System is intended for the fragmentation, emulsification and aspiration of subcutaneous fatty tissue for the purpose of aesthetic body contouring.

The Sound Surgical VASER 2.1 Lipo System is also indicated for use in the following surgical specialties for the fragmentation, emulsification and aspiration of soft tissues:

- Nuerosurgery;
- Gastrointestinal and affiliated organ surgery;
- Urological surgery;
- Plastic and reconstructive surgery;
- General surgery
- Gynecological surgery:
- Thoracic surgery; and
- Laparoscopic surgery.

Prescription Use___X___ AND/OR Over-the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE_

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110306

K 110306
1 of 5

510(k) Summary

JUN 23 2011

Submission Date:	28 January 2011
Submitter:	Sound Surgical Technologies LLC 357 South McCaslin Boulevard, Suite 100 Louisville, CO 80027
Submitter and Official Contact:	Mr. Stephen C. Smith Vice President of RA/QA Sound Surgical Technologies LLC 357 South McCaslin Boulevard, Suite 100 Louisville, CO 80027 +1 (720) 240-2970 SSmith@soundsurgical.com
Manufacturing Site:	Sound Surgical Technologies LLC 357 South McCaslin Boulevard, Suite 100 Louisville, CO 80027
Trade Name:	Sound Surgical Technologies LLC VASER 2.1 Lipo System
Common Name:	Suction lipoplasty system
Classification Name:	System, Suction, Lipoplasty
Classification Regulation:	21 CFR §878.5040
Product Code:	MUU

Substantially Equivalent Devices:

Sound Model	*Predicate 510(k) Number*	*Predicate Manufacturer and Model*
Sound VASER 2.1 Lipo System	K022051	Sound Surgical Technologies LLC / Sound VASER System

Device Description:

The Sound Surgical Technologies LLC (Sound) VASER 2.1 Lipo System (VASER 2.1) is an ultrasonic surgical system that fragments, emulsifies, and aspirates soft tissues.

The Sound VASER 2.1 is comprised of two (2) primary components: (1) the Sound VASER 2.1 Ultrasonic Amplifier; and (2) the VentX 2.1 Infiltration and Aspiration Console. Both the Sound VASER 2.1 Ultrasonic Amplifier and the Sound VentX 2.1 Infiltration and Aspiration Console are designed to operate independently, and may be sold or used separately, or together, as a system.

The VASER 2.1 Amplifier utilizes an ultrasonic surgical VASER Handpiece and Probe to fragment and emulsify the soft tissue. The VentX 2.1 Console utilizes sterile infiltration tubing, a handle and cannulae to infiltrate the tissue with fluids, and sterile suction tubing, a handle and cannulae to aspirate fluids and soft tissue.

Intended Use:

The Sound Surgical VASER 2.1 is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.

The Sound Surgical VentX 2.1 is intended for the suction or aspiration of fluids and tissue during surgical procedures. The VentX 2.1 is designed to operate with theSound Surgical VASER 2.1 or as a stand-alone system.

The Sound Surgical VASER 2.1 Lipo System is intended for the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring.

The Sound Surgical VASER 2.1 Lipo System is also indicated for use in the following surgical specialties for the fragmentation, emulsification, and aspiration of soft tissues:

- Neurosurgery;
- Gastrointestinal and affiliated organ surgery;
- Urological surgery;
- Plastic and reconstructive surgery;
- General surgery;
- Orthopedic surgery;
- Gynecological surgery;
- Thoracic surgery; and
- Laparoscopic surgery.

Technology Comparison:

The Sound VASER 2.1 Lipo System employs the same technological characteristics as the predicate device.

Performance Testing:

Sterilization

The Sound VASER 2.1 Consoles are not sterilized or sterilizable, and therefore this section does not apply to the Consoles.

The Sound VASER Handpiece and Probes, and VentX Handle and Cannulae are not provided sterile, but are sterilized by the user prior to use. The sterilization of the Handpiece and Cannulae will be validated prior to commercial distribution in accordance with *ISO 17665-1: 2006, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.*

The Sound VentX Infiltration and Suction Tubing are provided sterile. The sterilization of the Infiltration and Suction Tubing was validated in accordance with:

- *ISO 11137-1: 2006, Sterilization of health care products – Radiation, Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*; and
- *ISO 11137-2: 2006, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.*

Test results indicate that the Sound VASER 2.1 complies with the Standards.

Shelf-Life

The Sound VASER 2.1 Consoles, Sound VASER Handpiece and Probes, and VentX Handle and Cannulae are not provided sterile, and therefore this section does not apply.

The Sound Ventx Infiltration and Suction Tubing are provided sterile. The two (2) year shelf life of the Infiltration and Suction Tubing was validated in accordance with:

- *ISO 11607-1: 2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packages systems*; and
- *ISO 11607-2: 2006, Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.*

Test results indicate that the Sound VASER 2.1 complies with the Standards.

Biocompatibility

The Sound VASER 2.1 Consoles have no patient contact materials, and therefore this section does not apply to the Consoles.

The Sound VASER Handpiece and Probes, and VentX Infiltration and Suction Tubing, Handle and Cannulae have patient contact materials and are made from medical grade biocompatible materials.

Test results and analyses indicate that the VASER Handpiece and Probes, and VentX Infiltration and Suction Tubing, Handle and Cannulae materials comply in accordance with *ISO 10993-1: 2003, Biological evaluation of medical devices – Part 1: Evaluation and testing.*

Software Testing

The Sound VASER 2.1 contains MODERATE level of concern software. Software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05; and*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*

Test results indicate that the Sound VASER 2.1 complies with its predetermined specification.

Electrical Safety

The Sound VASER 2.1 was tested for patient safety in accordance with:

- *IEC 60601-1:1988, Am1: 1991, Am2: 1995, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*
- *UL 60601-1: 2006, Medical electrical equipment, Part 1: Particular requirements for safety.*
- *IEC 60601-1-1: 2000, Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems.*
- *IEC 60601-1-8: 2006, Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.*

Test results indicate that the Sound VASER 2.1 complies with the Standards.

Electromagnetic Compatibility Testing	The Sound VASER 2.1 was tested for EMC in accordance with: • *IEC 60601-1-2: 2007, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.* Test results indicate that the Sound VASER 2.1 complies with the Standard.
Performance Testing – Bench	The Sound VASER 2.1was tested for performance in accordance with its predetermined specifications as specified in *Section 11, Device Description – Performance Specifications*, of this submission. Test results indicate that the Sound VASER 2.1complies with its predetermined specification.
Conclusion	Verification and validation activities were conducted to establish the performance and safety characteristics the Sound VASER 2.1. The results of these activities demonstrate that the Sound VASER 2.1 is safe and effective when used in accordance with its intended use and labeling. Therefore, the Sound VASER 2.1 is considered substantially equivalent to the predicate device.