SOUND SURGICAL TECHNOLOGIES LLC. **February 9, 2023**
Attention: Harry Jeffreys
Solta Medical, Inc. a div. of Bausch Health US LLC
400 Somerset Corporate Blvd
Bridgewater, NJ 08807
Email Address: (b) (6) @bauschhealth.com

Re: BK220694 (Formally K120328)
Trade/Device Name: ORIGINS LIPOHARVESTING SYSTEM
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Jeffreys:

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 September 17, 2012. Specifically, FDA is updating this SE Letter because FDA has assigned your submission a new submission tracking number and created a new product code to better categorize your device technology.

Please update the registration and listing of the device within the FURLS Device Registration and Listing Module according to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm

For more information, please refer to the Federal Register Notice *Consolidation of Devices That Process Autologous Human Cells, Tissues, and Cellular and Tissue-Based Products at the Point of Care To Produce a Therapeutic Article* (86 FR 50887, available at https://www.federalregister.gov/documents/2021/09/13/2021-18912/consolidation-of-devices-that-process-autologous-human-cells-tissues-and-cellular-and-tissue-based).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact the Regulatory Project Manager, Julia Russell at 240-704-0618 or by email at Julia.Russell@fda.hhs.gov.

Sincerely,

Wilson W. Bryan, MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Enclosures

K120328

1 of 3

510(k) Summary

SEP 17 2012

Submission Date:	30 January 2012
Submitter:	Sound Surgical Technologies LLC 357 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 McCaslin Boulevard, Suite 100 Louisville, CO 80027 +1 (720) 240-2970 SSmith@soundsurgical.com
Manufacturing Site:	Sound Surgical Technologies LLC 357 McCaslin Boulevard, Suite 100 Louisville, CO 80027
Trade Name:	Sound Surgical Technologies LLC Origins LipoHarvesting 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*
Origins LipoHarvesting System	K092482	Shippert Medical Technologies / Tissu Trans Filtron
	K101713	human med AG / LipoCollector II Complete Set

Device Description: The Origins LipoHarvesting System consists of a reusable, closed loop tissue collection system comprised of a medical grade canister, a drain port and a lid intended to be used with a standard liposuction aspiration pump to collect fatty tissue for aesthetic body contouring. As the tissue is harvested from the patient, it enters the collection canister via a port in the canister lid. The physician removes unwanted waste materials from the collection system via the drain port at the base. This process leaves fatty tissue that can be transferred to syringes for autologous fat re-injection.

Intended Use: The Origins LipoHarvesting System is used in the aspiration, harvesting, filtering and transferring of autologous tissue. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

Technology Comparison: The Origins LipoHarvesting System employs the same technological characteristics as the predicate devices.

Characteristic Comparisons:

	Shippert Medical Technologies / Tissu Trans Filtron	***human med AG / LipoCollector II Complete Set***	***Origins LipoHarvesting Device***
Suction source(s)	Aspiration device	Aspiration device	Aspiration device
Volume Range	100 cc to 500 cc 100 cc to 1,000 cc 100 cc to 2,000 cc	Up to 1,000 mL	100 to 2,000 mL
Shipped sterile	Yes	Yes	No, sterilized by user prior to use
Initial Method	Gamma radiation	Ethylene oxide (EtO)	Not applicable
Sterility assurance level	10^{-6}	10^{-6}	10^{-6}
Disposable or reusable	Single use, disposable	Canister, lid and basket are reusable	Reusable
Resterilization Method	Not applicable	Autoclave	Autoclave

Performance Testing:

Sterilization The Origins LipoHarvesting System is not provided sterile, but is sterilized by the user prior to use. The sterilization of the Origins LipoHarvesting System 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.*

Shelf-Life	The Origins LipoHarvesting System is not provided sterile, and therefore this section does not apply.
Biocompatibility	The Origins LipoHarvesting System has patient contact materials and is made from medical grade biocompatible materials. Test results and analyses indicate that the Origins LipoHarvesting System materials comply in accordance with *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing*.
Software Testing	The Origins LipoHarvesting System does not contain software, and therefore this section does not apply.
Electromagnetic Compatibility Testing and Electrical Safety	The Origins LipoHarvesting System does not contain electrical components, and therefore this section does not apply.
Performance Testing – Bench	The Origins LipoHarvesting System is 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 Origins LipoHarvesting System complies with its predetermined specification.
Conclusion	Verification and validation activities were conducted to establish the performance and safety characteristics of the Origins LipoHarvesting System. The results of these activities demonstrate that the Origins LipoHarvesting System is considered substantially equivalent to the predicate devices.

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

SEP 17 2012

Sound Surgical Technologies, LLC
% Mr. Stephen C. Smith
Vice President of Regulatory Affairs and Quality Affairs
357 McCaslin Boulevard, Suite 100
Louisville, Colorado 80027

Re: K120328
Trade/Device Name: Origins LipoHarvesting System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: August 17, 2012
Received: August 28, 2012

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.

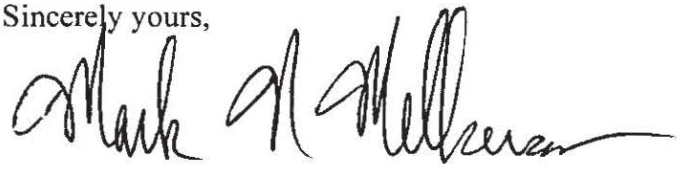
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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):	K120328
Device Name:	Origins LipoHarvesting System
Indications for Use:	The Origins LipoHarvesting System is used in the aspiration, harvesting, filtering and transferring of adipose autologous tissue for aesthetic body contouring. If harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

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)

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

510(k) Number K120328