Solta Medical
% Manal Morcos
Senior Director Regulatory Affairs, Surgical Equipment & Devices
Manal Morcos, MS BME, MBA
400 Somerset Corporate Boulevard
Bridgewater, New Jersey 08807

June 9, 2021

Re: K190551
Trade/Device Name: VASERlipo System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Manal Morcos:

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 May 1, 2019. 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

May 1, 2019

Solta Medical
% Ms. Marci Halevi
Senior Director Regulatory Affairs, Surgical Equipment & Devices
400 Somerset Corporate Boulevard
Bridgewater, New Jersey 08807

Re: K190551
Trade/Device Name: VASERlipo System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: March 5, 2019
Received: March 5, 2019

Dear Ms. Halevi:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Nielsen

Digitally signed by Joseph A. Nielsen
DN: cn=Joseph A. Nielsen, o=FDA, ou=FDA/CDRH/ODE/DSD/PRSB1, email=joseph.nielsen@fda.hhs.gov, c=US
Date: 2019.05.01 08:49:14 -04'00'

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190551

Device Name
VASERlipo System

Indications for Use *(Describe)*

The VASERlipo System is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.

The VentX console is intended for the suction or aspiration of fluids and tissue during surgical procedures. The VentX console is designed to operate with the VASERlipo System or as a stand-alone system.

The VASERlipo System is intended for the fragmentation, emulsification and aspiration of subcutaneous fatty tissue for the purpose of aesthetic body contouring.

The VASERlipo 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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

K190551

1. General Information

Submitter:	Contact Person:
Solta Medical Inc. 11720 North Creek Pkwy N., Suite 100 Bothell, WA 98011 Tel: 510-259-5299	Marci Halevi Director, Regulatory Affairs 400 Somerset Corporate Boulevard Bridgewater, New Jersey 08807 Phone: 908 952 5174 Marci.Halevi@bauschhealth.com

Preparation Date: 25 April 2019

2. Names

Device Name	VASERlipo System
Classification Name	System, Suction, Lipoplasty
Common Name:	Suction lipoplasty system
CFR References:	21 CFR 878.5040
Product Codes:	MUU
Performance Standards:	No performance standards for this device.

3. Predicate Device

K110306 VASERlipo System

4. Product Description

The subject of this Special 510(k) submission is for the VASERlipo System which is substantially equivalent to the predicate VASERlipo System.

The VASERlipo System is an ultrasonic surgical system that fragments, emulsifies, and aspirates soft tissues.

The VASERlipo System is comprised of two components: the VASER Ultrasonic Amplifier and the VentX Infiltration and Aspiration Console. Both components are designed to operate independently, and may be sold or used separately/together, or as a system.

The Amplifier uses an ultrasonic surgical handpiece and probe to fragment and emulsify the soft tissue. The Console uses sterile tubing, a handle, and cannula to infiltrate the tissue with fluids and aspirate the fluids/soft tissue.

5. Indications for Use

The VASERlipo System is intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring.

The VentX console is intended for the suction or aspiration of fluids and tissue during surgical procedures. The VentX console is designed to operate with the VASERlipo System or as a stand-alone system.

The VASERlipo System is intended for the fragmentation, emulsification and aspiration of subcutaneous fatty tissue for the purpose of aesthetic body contouring.

The VASERlipo 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

6. Summary of Technological Characteristics

The technological characteristics of the VASERlipo System are substantially equivalent to those of the predicate device.

Characteristic	Subject Device VASERlipo System	Predicate K110306
Intended Use	Intended for the fragmentation and emulsification of subcutaneous fatty tissues for aesthetic body contouring	Identical to subject device
Operating Frequency	36kHz Nominal	Identical to subject device
Infiltration Rates	50-550 ml/min	Identical to subject device
Suction Vacuum (max)	20 inHg at 5,000 ft	Identical to subject device
Cannula	1-6 mm diameter 7-40 cm length	2.4-4.6 mm diameter 17-34 cm length

7. Safety and Effectiveness Information

   The review of the indications for use and technical characteristics provided demonstrates the VASERlipo System is substantially equivalent to the predicate device.

8. Brief Summary of Nonclinical Tests and Results

   Safety tests of the VASERlipo System have demonstrated its compliance with applicable requirements of the following electrical standards:

IEC 60601-1:2005/AM1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
ISO 10079-1:2015	Medical suction equipment -- Part 1: Electrically powered suction equipment
Cannula deformation resistance	20°±5° and straightening without the shaft exhibiting any fractures, sharp edges, or loss of suction performance
Suction Vacuum (max) 20 inHg at 5,000 ft	20 inHg at 5,000 ft
Infiltration Rates	50-550 ml/min

9. Conclusion

   The VASERlipo System shares the same indications for use, design features, and functional features, and thus is substantially equivalent to the predicate device.

   Non-clinical test results demonstrate that the VASERlipo System is substantially equivalent to the predicate device and no new issues of safety or effectiveness have been raised.