May 1, 2019

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

Re: K190555
Trade/Device Name: PowerX Lipo 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/pmndc.frm 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...
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
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
### Indications for Use

**510(k) Number (if known)**  
K190555

**Device Name**  
PowerX Lipo System

**Indications for Use (Describe)**  
The PowerX Lipo System is intended for the removal of tissues or fluids from the body during general surgical procedures including suction lipoplasty for the purpose of aesthetic body contouring.

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**Type of Use (Select one or both, as applicable)**  
- [X] Prescription Use (Part 21 CFR 801 Subpart D)  
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**FORM FDA 3881 (7/17)**  
Page 1 of 1
1. General Information
Submitter: Solta Medical Inc.
11720 North Creek Pkwy N., Suite 100
Bothell, WA 98011
Tel: 510-259-5299

Contact Person: Marci Halevi
Director, Regulatory Affairs
400 Somerset Corporate Boulevard
Bridgewater, New Jersey 08807
Phone: 908-541-8695
Marci.Halevi@bauschhealth.com

Preparation Date: April 26, 2019

2. Names

Device Name: PowerX Lipo 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

K110255 PowerX Lipo System

4. Product Description

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

The PowerX Lipo System consists of three components: electronic controller with software, handpiece, and cannula.

The handpiece is connected to the controller and to an independent aspiration source. The controller sends electronic signals to the handpiece and thereby controls the motion of the cannula that is fitted to the distal end of the handpiece.

5. Indications for Use

The PowerX Lipo System is intended for the removal of tissues or fluids from the body during general surgical procedures including suction lipoplasty for the purpose of aesthetic body contouring.

6. Summary of Technological Characteristics
The technological characteristics of the PowerX Lipo System are substantially equivalent to those of the predicate device.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Subject Device PowerX Lipo System</th>
<th>Predicate K110255</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>Removal of tissue or fluid from the body</td>
<td>Identical to subject device</td>
</tr>
<tr>
<td>Operating Frequency</td>
<td>36kHz Nominal</td>
<td>Identical to subject device</td>
</tr>
<tr>
<td>Suction Vacuum (max)</td>
<td>20 inHg at 5,000 ft</td>
<td>Identical to subject device</td>
</tr>
<tr>
<td>Cannula dimensions</td>
<td>1-6 mm diameter 7-40 cm length</td>
<td>2.4 –4.6 mm diameter 17 – 34 cm length</td>
</tr>
</tbody>
</table>

7. Safety and Effectiveness Information
   The review of the indications for use and technical characteristics provided demonstrates the PowerX Lipo System is substantially equivalent to the predicate device.

8. Brief Summary of Nonclinical Tests and Results
   Safety tests of the System have demonstrated its compliance with applicable requirements of the following electrical standards:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 60601-1:2005/AM1:2012</td>
<td>Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance</td>
</tr>
<tr>
<td>ISO 10079-1:2015</td>
<td>Medical suction equipment -- Part 1: Electrically powered suction equipment</td>
</tr>
<tr>
<td>Cannula deformation resistance</td>
<td>20°±5° and straightening without the shaft exhibiting any fractures, sharp edges, or loss of suction performance</td>
</tr>
<tr>
<td>Suction Vacuum (max)</td>
<td>20 inHg at 5,000 ft</td>
</tr>
</tbody>
</table>

9. Conclusion
   The PowerX Lipo 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 PowerX Lipo System is substantially equivalent to the predicate device and no new issues of safety or effectiveness have been raised.