February 28, 2019

AngioDynamics, Inc.
Kasey Newcomb
Regulatory Affairs Specialist II
26 Forest St.
Marlborough, Massachusetts 01752

Re: K182250
Trade/Device Name: Solero MTA Cart, Solero MTA System, Solero microwave Tissue Ablation Applicator (14cm), Solero microwave Tissue Ablation Applicator (19cm), Solero microwave Tissue Ablation Applicator (29cm)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: January 31, 2019
Received: February 1, 2019

Dear Kasey Newcomb:

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...
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,

Jennifer R. Stevenson -S3

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

Device Name
Solero Microwave Tissue Ablation (MTA) System and Accessories

Indications for Use (Describe)
The Solero Microwave Tissue Ablation (MTA) System is indicated for the ablation of soft tissue during open procedures. The Solero MTA System is not indicated for cardiac use.

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.

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B. CONTACT
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C. DEVICE NAME
Trade Name: Solero Microwave Tissue Ablation (MTA) System and Accessories
Common/Usual Name: Microwave Tissue Ablation System and Accessories
Classification Name: Electrosurgical Cutting and Coagulation Device
(21 CFR § 878.4400, Class II, Pro-Code NEY)
Classification Panel: General Surgery

D. PREDICATE DEVICE
510(k) Number: K162449
Trade Name: Solero Microwave Tissue Ablation (MTA) System
Common/Usual Name: Microwave Tissue Ablation (MTA) System
Classification Name: Electrosurgical Cutting and Coagulation Device
(21 CFR § 878.4400, Class II, Pro-Code NEY)
Classification Panel: General Surgery

E. REFERENCE DEVICE
510(k) Number: K133821
Trade Name: Emprint Ablation System
Common/Usual Name: Microwave Ablation System and Accessories
Classification Name: Electrosurgical Cutting and Coagulation Device
(21 CFR § 878.4400, Class II, Pro-Code NEY)
Classification Panel: General Surgery

F. DEVICE DESCRIPTION
The device description of the Solero MTA System from the previous cleared K162449, has not been modified with the exception of the addition of the Solero MTA Cart as an optional accessory to the Solero MTA System.

The Solero MTA Cart is an optional accessory, that allows for transport, storage, and maneuverability of the system pre- and post-use. The Solero MTA Cart provides a shelf that is designed to securely hold the Solero MTA Generator in place. Once on the cart, the Solero MTA Generator is at an appropriate working height. The Solero MTA Cart has an incorporated IV pole for holding the chilled saline source used for maintaining the Solero Applicator at an appropriate temperature. There is a cable management system built into the Solero MTA Cart that allows for the mains power cable and footswitch to be stored for transporting the device or storage. The Solero MTA System can be transported using the handle on the cart. There is a tray on the stand of the cart intended to hold
Directions for Use and Operators Manual. The Solero MTA Cart sits on four rotating casters that can all be locked into place during use, storage, or as appropriate during transit.

G. **INDICATION FOR USE**

The Solero Microwave Tissue Ablation (MTA) System and Accessories are indicated for the ablation of soft tissue during open procedures. The Solero MTA System is not intended for cardiac use.

H. **STERILIZATION/CLEANING/SHELF LIFE**

The Solero MTA Cart is a hardware device with no patient contact and is provided non-sterile, therefore sterilization validation was not required or performed.

The Solero MTA Cart Operators Manual states that the cart should be cleaned by wiping down all accessible surfaces with a clean cloth that is slightly dampened with 70% isopropyl alcohol cleaning solution.

The Solero MTA Cart is not manufactured with any electronic or materials that are expected to expire or degrade over time. The Solero MTA Cart’s casters have successfully completed 5,000 full “on” and “off” cycles without failure of the locking holding power, wear or permanent deformation that would adversely affect the locking performance of the casters. There is no assigned shelf-life.

I. **BIOCOMPATIBILITY**

The Solero MTA Cart is a hardware device with no patient contact and provided non-sterile. Biocompatibility testing was not performed.

J. **SUMMARY OF SIMILARITIES AND DIFFERENCES IN TECHNOLOGY CHARACTERISTICS**

Reference device, Emprint Ablation System Cart, cleared via K133821, was used to support safety and effectiveness of the subject device. Both the subject device and specified reference device include the following technological characteristics:

- The carts worksurface heights are appropriate for performing microwave tissue ablation procedures
- No rough surfaces, sharp corners and/or edges
- Four (4) rotating locking casters
- Frame/shelf that accommodates a specific microwave tissue ablation generator. The microwave tissue ablation generators are not permanently installed on the cart.
- Includes tray/shelf for accessories storage
- Cable management system (hooks) that allow power cords, connection leads, cables, footswitch, etc, to be properly stored for either transporting or storage of microwave tissue ablation system
- Cart movement is manageable by a single user

Technological characteristic that are different between the subject and specified reference device are as follows:

- Solero MTA Cart incorporates an IV pole for holding the chilled saline source used for maintaining the Solero Applicator at an appropriate temperature. The specified reference device utilizes a separate IV pole that is positioned next to the cart.
- All isolation electronics are contained within the Solero MTA Generator. The specified reference cart includes an isolation transformer. The Solero MTA Generator contains appropriate electrical isolation; therefore, a separate isolation transformer is not required.

K. **PERFORMANCE DATA**

The following performance testing was used to substantiate safety and effectiveness:

- IEC 60601-1: General Requirements for Basic Safety and Essential Performance
- Packaging Testing
- Functional Testing including (e.g. electromagnetic compatibility and coexistence in a simulated use environment)
L. CONCLUSIONS
The results of comparison of technology similarities and differences and the non-clinical performance testing demonstrates that the subject device (cart accessory), when used as an accessory for the predicate device (Solero MTA System), is substantially equivalent to the predicate device when used without it.