December 3, 2021

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

Re: K213067
Trade/Device Name: Solero Microwave Tissue Ablation (MTA) System and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: November 5, 2021
Received: November 8, 2021

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 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213067

Device Name
Solero Microwave Tissue Ablation (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.

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510(K) SUMMARY FOR THE SOLERO MICROWAVE TISSUE ABLATION (MTA) SYSTEM AND ACCESSORIES

A. SPONSOR

AngioDynamics, Inc.
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Marlborough, MA 01752
USA

B. CONTACT

Kasey E Newcomb
Specialist II, Global Regulatory Affairs
Tel: 508.658.7813
Email: knewcomb@angiodynamics.com

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):	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. PURPOSE

The purpose of this submission is to introduce into commercial distribution a modification to the Solero MTA System software, previously cleared under predicate 510(k) K162449; specifically, to make a correction related to software becoming corrupted during loading. The correction to this software includes multiple images of the identical software (cleared via K162449) included on the device so if the first version becomes corrupted a back-up copy of the identical software can load. Additionally, minor software changes were made to correct displayed languages and include Finnish language within the system.

The primary purpose of the software update is to mitigate risk of boot up failure. The impact of the software changes as described within this submission have been evaluated as part of the Risk Analysis activity in terms of new/existing risks and new/existing failure modes. The results of this Risk Analysis activity determined the proposed software correction did not present any new risks or modify an existing risk. The software modification does not necessitate a new or modified risk control measure.

Verification testing was achieved by executing tests to ensure the components and hardware continue to work properly and verify the software changes were effective. The board support software was validated to ensure proper function of the bootloader. Regression testing was performed to confirm language translations and to evaluate power output.

E. DEVICE DESCRIPTION

The Solero Microwave Tissue Ablation (MTA) System and Accessories is a software-controlled, microwave generator with an integrated peristaltic pump that surgically ablates soft tissue when connected with sterile applicators. It is used to deliver microwave energy into soft tissue for the purpose of microwave ablation.

The Solero MTA Generator is distributed with a main power cable and a footswitch, which may be used as an alternate means of controlling microwave activation in place of the microwave button on the front of the generator. Power is delivered through the disposable Solero Applicator which are provided separately. The Solero Applicator is a surgically invasive, sterile single patient use device used to thermally ablate targeted soft tissue. The probe is specifically designed to deliver microwave energy at a frequency of 2.45 GHz from its distal end into soft tissue. A chilled saline source is required to maintain the Solero Applicators at an appropriate temperature.

The Solero MTA System includes an optional accessory, the Solero MTA Cart, that is used to assist transport of the Solero Generator, and to provide a resting surface during operation and storage.

F. 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

This change is solely related to the software of the Solero MTA System. For this reason, there was no impact to the Solero MTA System sterilization, cleaning, shelf-life.

I. BIOCOMPATIBILITY

The patient contacting materials are identical to the predicate device. As this change is solely related to the software there is no impact to biocompatibility previously conducted in accordance with ISO 10993: Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process.

G. SUMMARY OF SIMILARITIES AND DIFFERENCES IN TECHNOLOGY CHARACTERISTICS AND PERFORMANCE BETWEEN THE PREDICATE AND SUBJECT DEVICE

The principle of operation of the subject device is identical to that of the predicate device. The changes made to the Solero MTA System were limited solely to software and improving the boot up process, correcting the management and accuracy of the translations, and adding a new language. These changes did not affect the materials, manufacturing, design, biocompatibility/sterilization, technical characteristics, functionality, performance, usability, or indication for use of the previously cleared device (K162449).

H. PERFORMANCE/SAFETY DATA

The proposed AngioDynamics Solero MTA System safety was evaluated against the following published consensus standard:

- IEC-60601-1: 2006/03/09 (R2012), Ed 3.0 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014/02/25 Ed.4 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60601-1-6 2013/10/29 Ed: 3.1 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability

I. SOFTWARE

Software correction verification and validation testing was conducted based on the impact of the software changes. Results from regression testing included power output testing to ensure that the changes did not create any unintended issues in the operation of the system overall. All testing completed successfully. Additionally, software testing was conducted in compliance with IEC 62304 2006/05/09 Ed: 1 Medical Device Software – Software Lifecycle Process

H. CYBERSECURITY

The proposed device does not contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)

I. CONCLUSION

The proposed device is equivalent with respect to the basic system design and function to that of the predicate device. The differences between the predicate device and subject device do not raise new questions of safety or effectiveness.