March 27, 2023

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

Re: K223581
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: February 27, 2023
Received: February 27, 2023

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.03.27 13:05:42 -04'00'

Mark Trumbore, 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)*
K223581

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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FORM FDA 3881 (6/20) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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

A. SUBMITTER

AngioDynamics, Inc.
26 Forest St.
Marlborough, MA 01752
USA

B. CONTACT

Kasey E Newcomb
Manager, Global Regulatory Affairs
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) Number:	K213067
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. DEVICE DESCRIPTION

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.

G. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed Solero MTA System and the predicate Solero Microwave System are identical to one another (and therefore substantially equivalent) in all aspects, not limited to design, materials, manufacturing, specifications, dimensions, and indication for use.

H. DEVICE MODIFICATIONS AND RISKS ASSOCIATED WITH THE DESIGN MODIFICATION(S)

An update has been made to the Solero MTA System software (Application SW from v1.0.5 to v2.0.1 and IFS from v2.5.2 to v3.0.0) to further reduce the probability of "Error 0001" during boot-up caused by NAND flash memory errors.

The impact of the changes as described within K223581 was 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 were compared to the current Risk Analysis; the conclusions drawn from this assessment, determined the proposed modifications did not impact or modify an existing risk nor necessitate a new or modified risk.

I. BIOCOMPATIBILITY

The Solero MTA Generator is a hardware device with no patient contact. The patient contacting materials (Solero MTA Applicator) 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 10993-1: Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process.

J. ELECTRICAL SAFETY AND ELECTRICAL COMPATIBILITY (EMC)

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

- IEC 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2: Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic Compatibility Requirements and Tests
- IEC 60601-1-6: Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
- IEC 60601-2-6: Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment
- IEC 62366-1: Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
- IEC 62304: Medical device software - Software life cycle processes

K. STERILIZATION/CLEANING/SHELF LIFE

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

As this change is solely related to the software all sterilization (EO) and shelf-life testing for the Solero MTA Applicator is not impacted and previously conducted testing is still applicable.

L. PERFORMANCE DATA (SOFTWARE)

Software correction verification and validation testing was conducted based on the impact of the software changes. Results from the following tests ensure that the changes did not create any unintended issues in the operation of the system overall:

- Unit Verification Testing
- BSP Verification Testing
- Integration Testing
- System Integration Testing
- Validation Testing
- Language Validation and Regression Testing

All testing completed successfully. Additionally, software testing was conducted in compliance with IEC 62304:2006+A1:2015 Medical Device Software – Software Life-cycle Processes.

M. 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.).

N. CONCLUSIONS

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.