March 7, 2023

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

Re: K221883
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 10, 2023
Received: February 10, 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: 2023.03.07 13:50:22 -05'00'

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
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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)*

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.**

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

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**Date:** March 06, 2023
**510(k) Number:** K221883

# 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
Tel: 508.658.7813
Email: knewcomb@angiodynamics.com

## C. DEVICE

| | |
|---|---|
| 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/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

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 through 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.

## 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. The difference is the proposed Solero MTA Applicator has been modified to improving manufacturability and fluid path reliability of applicator. Additionally, an umbilic able clip was added to aid in stabilizing the cable during use, if desired.

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

Modifications made to the Solero MTA System were limited to the internal components of the applicator for the purpose of improving manufacturability and fluid path reliability of the Solero MTA Applicator. Additionally, a clip was added to the umbilicate cable to aid in stabilizing the cable during use.

The impact of the changes as described within K221883 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 impactor modify an existing risk nor necessitate a new or modified risk.

## I. BIOCOMPATIBILITY

The Solero MTA Applicator is a sterile single-use disposable instrument. The A Solero MTA Applicator has met the biocompatibility testing requirements identified in ISO 10993: Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process. Specifically, the following tests were performed with acceptable results; cytotoxicity, sensitization, irritation, systemic toxicity, pyrogenicity, and hemolysis. Solero MTA Generator and Cart are hardware device with no patient contact and provided non-sterile. Biocompatibility testing was not performed.

## J. ELECTRICAL SAFETY AND ELECRICAL 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 Applicator is sterilized via ethylene oxide (EO). A series of tests, performed by AngioDynamics and independent test houses, have been conducted to assess the suitability of the sterile packaging to protect the proposed Solero MTA System and ensure sterility within its stated shelf life at point of use. These tests confirm the packaging integrity, sterility and distribution cycle. Testing demonstrated that the packaging is robust enough to withstand extreme distribution conditions at the most extreme environmental conditions while maintaining packaging integrity and sterility.

## L. PERFORMANCE DATA

A series of verification and validation tests were conducted on sterile finished Solero MTA Applicators in accordance with design control requirements to confirm that the device confirm conforms to specific requirements related to the intended use, physical characteristics, and performance and has equivalent performance with predicate device Solero MTA System. The Solero MTA System met all specified design and performance requirements below:

- Flow Rate
- Power Output
- Tensile Testing
- Coolant Temperature
- Ablations
- Leak Testing
- Dielectric Strength
- Pump Compatibility

## L. ANIMAL STUDY – EX-VIVO

AngioDynamics conducted a study of microwave ablations using the Solero MTA System in the ex-vivo bovine liver model. The purpose of this study is to evaluate and measure the tissue ablations created by the proposed Solero Microwave Ablation System as compared to the predicate device. Within this study the proposed Solero MTA System and the predicate Solero MTA System were used to perform three (i.e., minimum, medium, and maximum energy) ablation settings in ex-vivo bovine liver. Each setting was performed three (3) separate times, at minimum, to establish ablation size for both the test and control articles. Results from the study showed that the Solero MTA System is able to create ablations in ex vivo livers consistently. The measurements of ablation size were comparable to the predicate device at all 3 settings in length, width and volume of ablations.

## I. CONCLUSIONS

The results of the non-clinical verification/validation and animal tissue testing support the comparison of similarities and differences. The results demonstrate the subject device and predicate devices are substantially equivalent.