



Food and Drug Administration
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May 5, 2017

Ms. Kasey E. Newcomb
Specialist I, Regulatory Affairs
Angiodynamics, Inc.
26 Forest Street
Marlborough, MA 01752

Re: K162449

Trade/Device Name: Solero Microwave Tissue Ablation (MTA) System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY
Dated: March 31, 2017
Received: April 3, 2017

Dear Ms. 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. 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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS)

regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Jennifer R. Stevenson -S

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)
K162449

Device Name
Solero Microwave Tissue Ablation (MTA) System

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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510(k) Summary – Solero Microwave Tissue Ablation (MTA) System

Date Prepared: April 28, 2017

A. Submitter Information

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B. Trade Name System

Trade Name: Solero Microwave Tissue Ablation (MTA)
 System
Common Name: Microwave Tissue Ablation System and
 Accessories
Classification Name: Electrosurgical Cutting and Coagulation Device
 and Accessories
Regulation Number 21CFR 878.4400
Product Code: NEY
Class: II

C. Predicate Devices

Primary Predicate: K122762 Acculis Accu2I pMTA Applicator and SulisV^{pMTA} Generator

Reference Device: K113237 NeuWave Medical, Inc – Certus 140 System

Common Name:	Microwave Ablation System and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Regulation Number	21CFR 878.4400
Product Code	NEY
Class:	II

D. Device Description

The Solero Microwave Tissue Ablation (MTA) System is a software-controlled, microwave generator with an integrated peristaltic pump that surgically ablates soft tissue through sterile applicators. The system may be used during open procedures for the ablation of soft tissue.

The Solero 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. A chilled saline source is required to maintain the Solero Applicators at an appropriate temperature.

E. Indications for Use

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

F. Technological Characteristics

Feature	Subject Device	Predicate Device	Reference Device
	Solero Microwave Tissue Ablation (MTA) System	K122762 Acculis Accu2i pMTA Applicator and Sulis VpMTA Generator	K113237 NueWave Certus 140 2.45 GHz Ablation System and Accessories
Indications For Use	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.	Acculis Accu2i pMTA Applicator with Sulis V pMTA Generator software release 2.1 is indicated for the intraoperative coagulation of soft tissue.	The NeuWave Medical Certus 140'M 2.45 13Hz Ablation System and Accessories are intended for the ablation (coagulation) of soft tissue in percutaneous, open surgical and in conjunction with laparoscopic surgical settings.
Applicator Features	Applicator with umbilical cable, IV spike, saline tubing and cartridge connector	Applicator with umbilical cable, IV spike, saline tubing and cartridge connector	Applicator with a handle, a cannula, a radiating section and a faceted tip for insertion
Generator Features	Generator touch screen display provides information on ablation/coagulation time, microwave delivered power, and system specific information	Generator touch screen display provides information on ablation/coagulation time, microwave delivered power, temperature probe readings and system specific information	Generator touch screen display provides information on ablation time, power, probe temperature and system specific information
Operating Principle	Generator delivers microwave energy to the applicator tip to thermally target tissue, resulting in coagulation and ablation	Generator delivers microwave energy to the applicator tip to thermally target tissue, resulting in coagulation and ablation	Generator delivers microwave energy to the applicator tip to thermally target tissue, resulting in coagulation and ablation
Ablated/Coagulated Tissue	Near spherical volumes, scalable to approximately 4 cm diameter in ≤ 6 minutes	Near spherical volumes, scalable to approximately 4 cm diameter in ≤ 6 minutes	< 4cm ablation in all tissues (PR), < 7 cm ablations in liver, < 6 cm in kidney (LK)
Applicator Patient Contacting Materials	Silicone coated shaft	Silicone coated shaft	Stainless steel, insulated shaft
Applicators Length	Standard: 14 cm Intermediate: 19 cm Long: 29 cm	Standard: 14 cm Intermediate: 19 cm Long: 29 cm	15 cm 20 cm
Applicators Outer Diameter	Stainless steel shaft 1.83mm Stainless steel shaft with silicone coating ≤ 2 mm	1.83 mm	1.47mm
Thermocouple Location	2.7cm from the tip	2.7cm from the tip	Unspecified

Feature	Subject Device	Predicate Device	Reference Device
	Solero Microwave Tissue Ablation (MTA) System	K122762 Acculis Accu2i pMTA Applicator and Sulis VpMTA Generator	K113237 NueWave Certus 140 2.45 GHz Ablation System and Accessories
Max Tip Temperature	Temperatures below 48°C, they alert the user when the coolant begins to become warm (38°C), and an alarm will sound and microwave energy delivery will terminate when the coolant in the tip reaches 48°C	Temperatures below 48°C, they alert the user when the coolant begins to become warm (38°C), and an alarm will sound and microwave energy delivery will terminate when the coolant in the tip reaches 48°C	Unspecified
Cable Length	295.25cm for all applicator lengths	Standard: 200.1cm Intermediate: 192.0cm Long: 176.1cm	Unspecified
Generator Frequency	2.45 GHz	2.45 GHz	2.45 GHz
Reflected Power Threshold	-5.4 dB	-5.4 dB	Unspecified
System Output Power Range	60 to 140 watts in 20 watt increments	60 to 140 watts in 20 watt increments	95W per channel or up to 140W in a single channel
Microwave Generation	Solid-state microwave generator	Magnetron	Unspecified

G. Safety and Performance

The results of verification and validation activities were performed in accordance with design control requirements per 21 CFR 820.30 and demonstrate that the proposed device Solero Microwave Tissue Ablation (MTA) System meets predetermined performance specifications.

Performance testing that was completed included:

- Tip Puncture Force
- Flexural Tip Strength
- Removal Force
- Flow Rate
- Bag Spike
- Cartridge Connection Force
- Cartridge Alignment
- Device Recognition
- Power Output
- Shaft to Applicator Tip Tensile
- Handle to Shaft Tensile
- Umbilical to Handle Tensile
- Umbilical to Cartridge Tensile
- Pump Tubing to Cartridge Tensile
- Pump Tubing to Bag Spike Tensile
- Saline Temperature
- Multiple Ablations
- Track Ablation
- Temperature Control
- Dielectric Strength
- Cartridge Connection
- Pump Compatibility
- Cartridge Attachment Force
- Cartridge Removal Force
- Generator Hardware testing
- Complex programmable logic device
- Reliability Testing

The performance evaluation plan included testing per the following recognized standards to assess conformance to IEC 60601 (3rd Edition).

IEC 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Safety
IEC 60601-1-2	Medical Electrical Equipment – Part 2: General Requirements for Basic Safety and Essential Performance – Collateral Standard Electro Magnetic Compatibility – Requirements and Test

Human Factors Evaluation:

Simulated Use / Human Factors Testing has been conducted to evaluate the application of the Solero Microwave Tissue Ablation (MTA) System (i.e., Solero System) when used to ablate soft tissue.

Animal Studies:

Performance characterization was performed on three difference ex-vivo tissue; bovine liver, porcine kidney, and porcine lung, as these are considered to be comparable to human tissue. Testing was performed at varying time settings and power limits. The purpose of this testing was to support the recommended ablation settings, as well as demonstrate substantial equivalence to the predicate device.

Two GLP compliant animal studies were performed. The first study was to evaluate and establish substantial equivalence of the Solero Microwave Tissue Ablation (MTA) System to its predicate device Acculis Accu2I pMTA Applicator and SulisV^{pMTA} Generator (K122762) and reference device Certus 140 System (K113237). The study also looked at the fundamental operational characteristics for the Solero MTA System. Safety was assessed from: animal behavior, ECG's, respiration rates, and temperature.

The second study's objective was to evaluate the safety and performance of the Solero Microwave Tissue Ablation (MTA) System to its predicate device Acculis Accu2I pMTA Applicator and SulisVpMTA Generator (K122762) during open surgical procedure in an acute porcine model. This study specifically evaluated and compared the safety at the highest power (140W) and time (6 minutes) of the two devices.

H. Substantial Equivalence Conclusion

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