Solero

Microwave Tissue Ablation System

VALUE ANALYSIS BRIEF

angiodynamics

Solero Value Analysis Contents

SOLERO VALUE ANALYSIS SUMMARY

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.

The Solero MTA System is a software-controlled, microwave generator which surgically ablates soft tissue through sterile applicators that are saline cooled. The Solero Applicator is designed to fit into a CT gantry with visibility under ultrasound. The applicator is available in 14, 19, and 29 cm lengths with an integrated microwave power delivery cable and coolant tubing set that is 2.86 m (9.3 ft) in length.

Features of the Solero MTA System include:

- A single applicator system with the ability to create up to a 5 cm ablation in 6 minutes†
- 2.45 GHz operating frequency
- Generator output power up to 140 W
- Integrated peristaltic pump
- Intuitive touch screen user interface with power and time settings
- Real-time output power display
- Applicator coolant temperature monitoring
- Reflected energy monitoring
- No grounding/dispersive/neutral electrode required
- Applicator for ablation in soft tissues

SOLERO MICROWAVE TISSUE ABLATION SYSTEM

The Solero MTA System is unique because it is specially designed to complete up to a 5 cm ablation in 6 minutes at max power output using a single applicator.† The Solero MTA System is able to accomplish this through the innovative solid state generator and specially designed applicator.

Power:

The Solero MTA System is specifically designed to deliver optimized power to the tissue, maximizing the ablation volume in the shortest period of time. Reflected power is monitored and visualized in the delivered power window on the generator throughout the procedure to ensure maximum efficiency.

Frequency:

Microwave energy at 2.45 GHz is deposited nearly spherically into the tissue, utilizing a dielectric antenna and optimized ceramic tip. The tip to shaft transition is reinforced with a stainless steel, copper coated outer conductor for added strength.

Temperature:

As microwave energy is transmitted, it creates heat along the cable and length of the shaft. The Solero MTA System utilizes patented cooling channel technology which includes a thermocouple for continuous temperature monitoring. The system will alert the user if overheating occurs, minimizing the risk to surrounding tissues while maintaining nearly spherical ablations.

†Ex vivo bovine liver – actual clinical results in perfused tissues may differ

SOLERO MICROWAVE GENERATOR FEATURES AND BENEFITS

The Solero Microwave (MW) Generator with a 2.45 GHz operating frequency is a solid state generator that can power up to 140 W. It has an intuitive touch screen interface and integrated peristaltic pump for continuous device cooling with having the capability to monitor both coolant temperature and reflected energy.

FEATURE	BENEFIT
2.45 GHz solid state generator	Reliable operation with no need for annual calibration
Powers up to 140 W	Optimized power delivery for speedy ablations up to 5 cm†
Integrated peristaltic pump	Continuous cooling capacity
Single action cartridge connection	Simple and intuitive device setup
Continuous temperature monitoring	Minimizes risk to non-targeted tissues along the cable and the length of the applicator
Real-time reflected energy monitoring	Provides user feedback on the efficiency of the ablation
Touch screen user interface	Simple to operate
Countdown timer and delivered power monitoring	Easy to understand setup and operation
Time and wattage settings	Simple procedure parameters

SOLERO MICROWAVE TISSUE ABLATION SYSTEM—

The single applicator system with the ability to complete up to a **5 cm ablation in 6 minutes**†

†Ex vivo bovine liver- actual clinical results in perfused tissues may differ

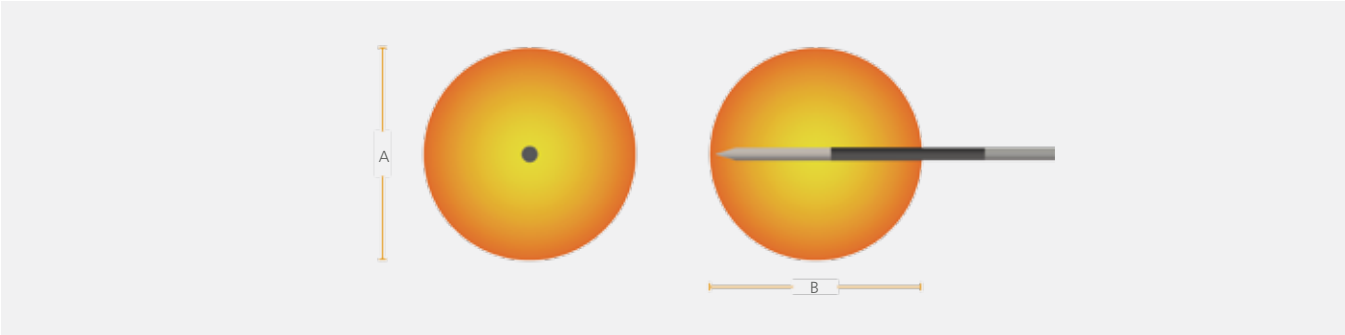
SOLERO MICROWAVE APPLICATOR FEATURES AND BENEFITS

The Solero MTA System offers scalability with a single applicator designed for multiple predictable ablation zones. The Solero MW Applicator is available in 14, 19, and 29 cm lengths. The Solero MTA System is easy to setup and only requires a single applicator to reduce MW applicator placement time. The low profile handle and rigid 15 g stainless steel applicator includes centimeter markings to aid in device positioning, and the 2.86 meter (9.3 feet) power delivery cable is fully cooled by the integrated coolant tubing set.

FEATURE	BENEFIT
15 g stainless steel applicator	Small and rigid enough to provide trackability for predictable applicator placement
Available in 14, 19, and 29 cm lengths	Variety of lengths available
Molded ergonomic handle	Fits easily through the CT gantry
Patented coolant channel with thermocouple	Provides real-time feedback on the device coolant temperature, minimizing the risk to tissues not intended for ablation
Centimeter markings along the shaft	Visibility of placement depth during procedures
Optimized ceramic tip	Diffuses MW energy nearly spherically around the dielectric antenna
Dielectric antenna with a stainless steel, copper coated outer conductor	Optimized power delivery into the tissue with added strength
2.86 m (9.3 feet) flexible, fully cooled cable	Easy placement while minimizing the risk of non-targeted tissue burns
Integrated single piece coolant tubing with molded bag spike	Simple setup and reliable operation

SOLERO MTA SYSTEM RESULTS

The Solero MTA System, which features the Solero MW Applicator, delivers focused microwave energy to generate lethal heat levels, greater than 70°C, in order to destroy tissue. Microwave energy generates heat in soft tissue through the rapid oscillation of water dipoles, which causes frictional heat within the target zone of ablation. The active zone of microwave energy radiates approximately 2 cm around the device's energy emitting antenna. The remaining heat generation is considered conduction heat transference, where core heated tissue delivers heat to adjacent tissue over time, increasing the overall size of the ablation. The size of the ablation is repeatable and predictable based on pre-established protocols using ex vivo bench testing in bovine liver and porcine kidney and lung.



EX VIVO BOVINE LIVER

	2 min (A x B)	4 min (A x B)	6 min (A x B)
60 W	2.4 Ø x 2.8 cm	3.0 Ø x 3.6 cm	3.5 Ø x 3.9 cm
100 W	3.0 Ø x 3.7 cm	3.5 Ø x 4.4 cm	4.2 Ø x 4.9 cm
140 W	3.2 Ø x 4.0 cm	4.0 Ø x 5.0 cm	4.4 Ø x 5.4 cm

EX VIVO PORCINE KIDNEY

	2 min (A x B)	4 min (A x B)	6 min (A x B)
60 W	2.4 Ø x 3.1 cm	3.0 Ø x 3.8 cm	3.2 Ø x 4.0 cm
100 W	2.6 Ø x 3.7 cm	3.4 Ø x 4.5 cm	3.5 Ø x 5.0 cm
140 W	2.9 Ø x 4.3 cm	3.5 Ø x 5.0 cm	3.9 Ø x 5.6 cm

EX VIVO PORCINE LUNG

	2 min (A x B)	4 min (A x B)	6 min (A x B)
60 W	1.3 Ø x 1.9 cm	1.5 Ø x 2.1 cm	1.6 Ø x 2.4 cm
100 W	1.6 Ø x 2.7 cm	2.0 Ø x 3.2 cm	2.3 Ø x 3.2 cm
140 W	1.7 Ø x 3.2 cm	2.5 Ø x 3.6 cm	2.6 Ø x 3.6 cm

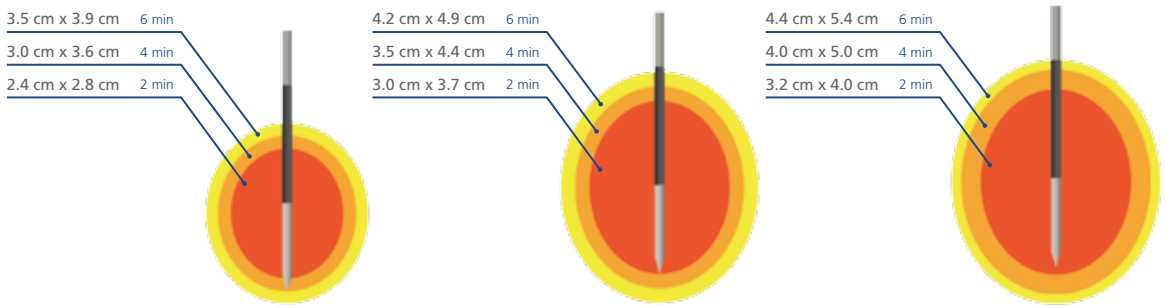
Note: Ablation volumes in perfused tissues may differ from static laboratory results.

SPEEDY AND SCALABLE ABLATION VOLUMES

To evaluate the performance of the Solero MTA System's speedy, predictable, and scalable ablation volumes, time (2, 4, and 6 min) and wattage (60, 100, and 140 W) were varied and ablation volumes were assayed by diameter and length measurements. The Solero MTA System is unique because it is specially designed to complete a 5 cm ablation in 6 minutes at max power output using a single applicator.† The Solero MTA System is specifically designed to deliver optimized power to the tissue to maximize the ablation volume in the shortest period of time. Furthermore, the data demonstrates the additional benefit of the Solero MTA System's ability to generate predictable and scalable volumes by simply varying time and wattage.

Ex Vivo Bovine Liver (diameter x length)

Note: Ablation volumes in perfused tissues may differ from static laboratory results.



60 W **100 W** **140 W**

†Ex vivo bovine liver- actual clinical results in perfused tissues may differ

SOLERO MTA SYSTEM COMPETITIVE COMPARISON

Brand Name	Company	Frequency	Applicator Size	Number of Applicators	Single Applicator Ablation	Time to Max Ablation	Cooling Mechanism
Solero	AngioDynamics	2.45 GHz	15 g	Single	4.4 x 5.4 cm†	6 min†	Saline
Emprint	Medtronic	2.45 GHz	13 g	Single	3.5 x 4 cm	10 min	Water
Certus140	Ethicon	2.45 GHz	17 g	Up to 3	4 x 7 cm	10 min	CO2
Amica	HS Amica	2.45 GHz	11, 14, 16 g	Single	5 x 4 cm	10 min	Saline
MicroThermX	Perseon	915 MHz	14 g	Up to 3	3.8 x 6.3 cm	15 min	Saline
Avecure	MedWaves	908–928MHz	12, 14, 16 g	Single	6 x 9 cm	30 min	None

Brand Name	Company	Frequency 2.45 GHz	15 g or Smaller Applicator	Single Applicator 5 cm Ablation	Up to a 5cm Ablation in 6 min
Solero	AngioDynamics	Yes	Yes	Yes†	Yes†
Emprint	Medtronic	Yes	No	No	No
Certus140	Ethicon	Yes	Yes	No	No
Amica	HS Amica	Yes	Yes	Yes	No
MicroThermX	Perseon	No	No	No	No
Avecure	MedWaves	No	Yes	No	No

Competition information derived from publicly available product literature.

ORDER INFORMATION

SKU	Description
H78712740000US0	Solero MW Generator
H787700106001US0	Solero MW Applicator 14 cm
H787700106002US0	Solero MW Applicator 19 cm
H787700106003US0	Solero MW Applicator 29 cm

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510K CLEARANCE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

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.

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

REFERENCES

1. Solero MTA System Generator Operator's Manual; 16750971-21B.
2. Solero MTA Applicator Directions For Use; 14600971-01A.

Please refer to the Solero Generator Operator's Manual and the Solero Applicator Directions For Use for complete instructions, warnings, and precautions.

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www.angiodynamics.com