Solero
Microwave Tissue Ablation System

VALUE ANALYSIS BRIEF

angiodynamics
Solero Value Analysis Contents

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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.
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.

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

**Diagram**

- Copper Coated Outer Conductor
- 15 g Stainless Steel Shaft
- Feed Zone
- Ceramic Tip
- Thermocouple
- Molded Ergonomic Handle
- 2.86 m (9.3 ft) Cooled Cable
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.

<table>
<thead>
<tr>
<th>EX VIVO BOVINE LIVER</th>
<th>EX VIVO PORCINE KIDNEY</th>
<th>EX VIVO PORCINE LUNG</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2 min</strong></td>
<td><strong>4 min</strong></td>
<td><strong>6 min</strong></td>
</tr>
<tr>
<td>(A x B)</td>
<td>(A x B)</td>
<td>(A x B)</td>
</tr>
<tr>
<td>60 W</td>
<td>60 W</td>
<td>60 W</td>
</tr>
<tr>
<td>2.4 Ø x 2.8 cm</td>
<td>2.4 Ø x 3.1 cm</td>
<td>3.0 Ø x 1.9 cm</td>
</tr>
<tr>
<td>3.0 Ø x 3.6 cm</td>
<td>3.0 Ø x 3.8 cm</td>
<td>3.5 Ø x 2.1 cm</td>
</tr>
<tr>
<td>3.5 Ø x 3.9 cm</td>
<td>3.2 Ø x 4.0 cm</td>
<td>3.5 Ø x 3.9 cm</td>
</tr>
<tr>
<td>100 W</td>
<td>100 W</td>
<td>100 W</td>
</tr>
<tr>
<td>3.0 Ø x 3.7 cm</td>
<td>2.6 Ø x 3.7 cm</td>
<td>1.5 Ø x 2.7 cm</td>
</tr>
<tr>
<td>3.5 Ø x 4.4 cm</td>
<td>3.4 Ø x 4.5 cm</td>
<td>2.0 Ø x 4.5 cm</td>
</tr>
<tr>
<td>4.2 Ø x 4.9 cm</td>
<td>3.5 Ø x 5.0 cm</td>
<td>3.5 Ø x 4.9 cm</td>
</tr>
<tr>
<td>4.4 Ø x 5.4 cm</td>
<td>3.9 Ø x 5.6 cm</td>
<td>4.4 Ø x 5.4 cm</td>
</tr>
<tr>
<td>140 W</td>
<td>140 W</td>
<td>140 W</td>
</tr>
<tr>
<td>3.2 Ø x 4.0 cm</td>
<td>2.9 Ø x 4.3 cm</td>
<td>1.7 Ø x 3.2 cm</td>
</tr>
<tr>
<td>4.0 Ø x 5.0 cm</td>
<td>3.5 Ø x 5.0 cm</td>
<td>2.5 Ø x 3.6 cm</td>
</tr>
<tr>
<td>4.4 Ø x 5.4 cm</td>
<td>3.2 Ø x 4.0 cm</td>
<td>2.6 Ø x 3.6 cm</td>
</tr>
</tbody>
</table>

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
  - 3.5 cm x 5.4 cm (6 min)
  - 3.0 cm x 4.6 cm (4 min)
  - 2.4 cm x 2.8 cm (2 min)

- 100 W
  - 4.4 cm x 4.9 cm (6 min)
  - 4.0 cm x 4.0 cm (4 min)
  - 3.2 cm x 3.6 cm (2 min)

- 140 W
  - 4.4 cm x 5.4 cm (6 min)
  - 4.0 cm x 5.0 cm (4 min)
  - 3.2 cm x 4.0 cm (2 min)

*Ex vivo bovine liver- actual clinical results in perfused tissues may differ*
## SOLERO MTA SYSTEM COMPETITIVE COMPARISON

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

**Comparison Information**

- Competition information derived from publicly available product literature.

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## ORDER INFORMATION

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<th>Description</th>
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<tr>
<td>H78712740000US0</td>
<td>Solero MW Generator</td>
</tr>
<tr>
<td>H787700106001US0</td>
<td>Solero MW Applicator 14 cm</td>
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<tr>
<td>H787700106002US0</td>
<td>Solero MW Applicator 19 cm</td>
</tr>
<tr>
<td>H787700106003US0</td>
<td>Solero MW Applicator 29 cm</td>
</tr>
</tbody>
</table>

† Ex vivo bovine liver- actual clinical results in perfused tissues may differ
May 5, 2017

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

Re: K163449
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 8093]); 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" (21 CFR 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**

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.

<table>
<thead>
<tr>
<th>Type of Use (Select one or both, as applicable)</th>
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<tr>
<td>☑ Prescription Use (Part 21 CFR 801 Subpart D)</td>
</tr>
<tr>
<td>☐ Over-The-Counter Use (21 CFR 801 Subpart C)</td>
</tr>
</tbody>
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*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRAStaff@fda.hhs.gov

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*
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.