Emprint™ Ablation System
WITH THERMOSPHERE™ TECHNOLOGY

VALUE ANALYSIS BRIEF

Request Letter
Product Overview
Clinical Performance
Cross Reference
510(k)
I am requesting the new Emprint™ ablation system with Thermosphere™ technology for our facility so that I have consistent access to this system for my cases.

Emprint™ ablation system with Thermosphere™ technology, brought to you by Covidien, is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.¹

Patented Thermosphere™ technology is the breakthrough innovation that empowers the Emprint™ ablation system. Thermosphere™ technology employs three kinds of control to maintain predictable, spherical ablation zones regardless of changes in tissue during the procedure.¹²³

- **Thermal control** — Advanced antenna cooling prevents the antenna shaft from contributing to the ablation zone.
- **Field control** — Advanced antenna geometry focuses energy at the tip of the device into a precise spherical electromagnetic field.
- **Wavelength control** — Active antenna buffering maintains the spherical electromagnetic field throughout the course of the ablation.

Features of the Emprint™ ablation system include:

- The Emprint™ ablation system creates predictable ablation zones across a wide range of tissue types.¹
- The Emprint™ ablation system is expected to achieve near-triple Evident antenna performance with a single antenna, allowing you to effectively ablate more, with less, in less time.²
- The Emprint™ ablation system creates spherical ablation zones, allowing you more freedom to plan and safely execute procedures regardless of angle of approach.¹
- The ability to create large spherical ablation zones with a single antenna may reduce procedure times.²
- The Emprint™ ablation system is easy to setup and use.³

The Emprint™ ablation system antennas come in three lengths to accommodate a variety of procedural applications.

Thank you for reviewing this information. Please feel free to contact me if you have any questions.

Sincerely,

Additional Comments:

1. Based on internal porcine testing "In vivo Performance Testing of the Emprint™ Microwave Ablation System in a Porcine Model," conducted during November 2013; R0043973.
2. Emprint™ device IFU: Percutaneous Antenna with Thermosphere™ Technology; 1058196.
PRODUCT OVERVIEW

Overview

The Emprint™ ablation system with Thermosphere™ technology is a breakthrough product for the ablation of liver tumors and other soft tissue, including lung, kidney and liver.¹ Thermosphere™ technology, the revolutionary technology inside of the Emprint™ ablation system, gives clinicians three kinds spatial energy control – thermal control, field control and wavelength control–to create consistent, reproducible spherical ablation zones regardless of tissue type or changes in tissue during a procedure.¹,²

- Thermal control minimizes uncontrolled thermal factors that contribute to a passive ablation zone.
- Field control delivers a precise, scalable spherical field.
- Wavelength control prevents wavelength elongation as tissue becomes desiccated or charred and its properties change during ablation.

The system uses a high power generator and high efficiency reusable cable to improve energy delivery and ablative performance for increased speed.² The Emprint™ ablation system is expected to achieve triple Evident™ MWA system antenna performance with a single antenna.² Due to the delivery of predictable spherical ablation zones, clinicians have more choice of approach further simplifying needle placement and saving time in both planning and procedure.

Utilizing more than 50 Covidien patents, the Emprint™ ablation system is designed to overcome the uncertain clinical outcomes of other ablative technologies, allowing clinicians to feel confident in predictable outcomes in every procedure.
PRODUCT OVERVIEW

Ablation Cart
An all in one system designed with a 17”x19” footprint to save space in crowded procedural suites. Easy to set up to save time. Order Code: CART1

Ablation Generator with Thermosphere™ Technology
100W generator with an intuitive user interface and customizable power settings for simplified set-up and operation. Order Code: CAGEN1

Percutaneous Antenna with Thermosphere™ Technology
An internally cooled antenna with single body fiberglass construction that reduces risk the of antenna breakage during placement.

<table>
<thead>
<tr>
<th>Length</th>
<th>Order Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short (15 cm)</td>
<td>CA15L1</td>
</tr>
<tr>
<td>Standard (20 cm)</td>
<td>CA20L1</td>
</tr>
<tr>
<td>Long (30 cm)</td>
<td>CA30L1</td>
</tr>
</tbody>
</table>

Ablation Pump
A proven pump for efficient antenna cooling to minimize thermal conductivity for increased control and predictability. Order Code: CAPUMP1

Ablation Reusable Cable
A high efficiency reusable cable optimizes power delivery and ablative performance. Order Code: CA190RC1

Footswitch
Footswitch allows easy activation to save overall procedure time. Order Code: RFASW

Remote Temperature Probe
Verify tissue temperature in real time and trigger automatic ablation shut off when a preset tissue temperature is achieved. Order Code: RTP20
PERFORMANCE

The Emprint™ ablation system has demonstrated improved performance in both in-vivo and ex vivo tissue models in comparison to Microwave Ablation Technology on the market today. By employing novel Thermosphere™ technology, the Emprint™ ablation system is able to maintain a spherical active heating zone which is unchanging across various tissue types and uninfluenced by tissue desiccation during the ablation procedure. Combined with precise power delivery from the Emprint™ generator, Thermosphere™ technology creates predictable ablation zones across a wide range of tissue types. The performance of the Emprint™ ablation system with Thermosphere™ technology has been demonstrated in in-vivo and ex vivo studies as it relates to ablation size and shape.¹

A systematic review of In-vivo and Ex-vivo Data was collected on the Emprint™ ablation system and summarized for 3 soft tissue types (lung, liver, and kidney).

To evaluate ablation shape across tissue type, dose, and device, the height and width ratios were calculated on the ex-vivo data. The ablation diameter (width) was also evaluated on the same ex-vivo data set as a function of ablation size. The results are captured in Table 1 for an ablation time of 10 minutes with the ablation system operating at full capacity. A ratio near 1 indicates a spherical ablation zone.

Table 1: Emprint™ Ex vivo Size and Shape Comparison at 10:00/maximum power output across three tissue types

<table>
<thead>
<tr>
<th>TISSUE</th>
<th>HEIGHT</th>
<th>WIDTH</th>
<th>RATIO</th>
</tr>
</thead>
<tbody>
<tr>
<td>LIVER</td>
<td>4.2</td>
<td>4.2</td>
<td>1</td>
</tr>
<tr>
<td>LUNG</td>
<td>4.1</td>
<td>3.4</td>
<td>0.90</td>
</tr>
<tr>
<td>KIDNEY</td>
<td>3.0*</td>
<td>3.0*</td>
<td>1*</td>
</tr>
</tbody>
</table>

Table 1: Emprint™ Ex vivo Size and Shape Comparison at 10:00/maximum power output across three tissue types

To compare ablation size between the Emprint™ and Evident™ systems, the ablation diameter was compared within the in vivo data set and graphed as a function of time. Results revealed that a single Emprint™ antenna outperforms a single Evident™ antenna and is equivalent to 3 simultaneously activated Evident™ antennas at maximum power output.⁵

In summary, a review of the current data on the Emprint™ system with Thermosphere™ technology suggests:

• The Emprint™ microwave ablation system creates predictable spherical ablation zones across a wide range of tissue types.¹
• A single Emprint™ antenna achieved equivalent ablation zone size compared to three simultaneously activated Evident™ antennas.⁵
• The ability to create large spherical ablation zones with a single antenna may reduce the need for multiple antennas.²
• The ability to create large spherical ablation zones with a single antenna may reduce procedure times and costs.²
## CROSS-REFERENCE

<table>
<thead>
<tr>
<th>MANUFACTURER</th>
<th>Covidien</th>
<th>Microsulis Medical LTD</th>
<th>HS Medical, Inc.</th>
<th>Neuwave</th>
<th>MedWaves Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT</td>
<td>Emprint™ Ablation System</td>
<td>Acculis MTA™ System</td>
<td>HS™ AMICA</td>
<td>Certus™ 140</td>
<td>MedWave Avecur™</td>
</tr>
<tr>
<td>PROPRIETARY TECHNOLOGY</td>
<td>Thermosphere™ Technology</td>
<td>--</td>
<td>MINI-CHOKE™ technology</td>
<td>CO₂ cooling system Tissu-Loc™</td>
<td>Real-time temperature and power monitoring</td>
</tr>
<tr>
<td>ANTENNA</td>
<td>Straight internally cooled antenna</td>
<td>Closed circuit antenna cooling</td>
<td>Straight internally cooled antenna</td>
<td>Straight internally cooled antenna</td>
<td>Straight antenna</td>
</tr>
<tr>
<td>AVAILABLE LENGTHS</td>
<td>15 cm, 20 cm, 30 cm</td>
<td>AccuZi pMTA: 14 cm, 19 cm, 29 cm</td>
<td>15 cm, 20 cm, 27 cm</td>
<td>15 cm, 20 cm</td>
<td>12 G, 14 G, 16 G</td>
</tr>
<tr>
<td>POWER</td>
<td>Up to 100 W, 2450 MHz</td>
<td>30 to 180 W, 2450 MHz</td>
<td>Up to 100 W, 2450 MHz</td>
<td>Up to 100 W, 2450 MHz</td>
<td>5 cm, 23 cm, 30 cm</td>
</tr>
<tr>
<td>COOLING</td>
<td>Thermal control to minimize uncontrolled thermal factors that contribute to a passive ablation zone and limit heat-sink effect</td>
<td>AccuZi pMTA: cooled Internally-cooled Coolant temperature monitored at the location on the shaft just past the radiating tip</td>
<td>Internal water cooling combined with a special miniaturized trap for reflected waves (MINI-CHOKE™)</td>
<td>CO₂ cooling</td>
<td>No cooling</td>
</tr>
<tr>
<td>TEMPERATURE MONITORING</td>
<td>Remote temperature probe monitors tissue temperature at the tip</td>
<td>Acculis MTA™ temperature probes - these bespoke 18 gauge thermistors are used to monitor tissue temperatures of critical locations during coagulations.</td>
<td>Built-in thermocouple for probe temperature monitoring</td>
<td>Built-in temperature monitoring system</td>
<td>Temperature control mode: Power level is modulated to achieve and maintain a temperature set-point sensed by a sensor located within ablation probe</td>
</tr>
</tbody>
</table>
Covidien LLC
Ms. Heather Nigro
Senior Director, Global Regulatory Affairs
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K133821
Trade/Device Name: Emprint Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Microwave Ablation System And Accessories
Regulatory Class: Class II
Product Code: NEY
Dated: March 27, 2014
Received: March 28, 2014

Dear Ms. Nigro:

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 Part 801); 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (if known):  K133821

Device Name: Emprint™ Ablation System

Indications for Use:
The Covidien Emprint™ Ablation System is intended for use in percutaneous, laparoscopic, and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.

The Covidien Emprint™ Ablation System is not intended for use in cardiac procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S
References

2. Emprint™ device IFU: Percutaneous Antenna with Thermosphere™ Technology; 1058196.
4. As compared to the Evident™in R0045127 Antenna mechanical test report.
5. Boulder Pre-Verification Ablation Test Results Summary 04-19-2013.ppt | 1020540 Evident MWA Percutaneous Antenna VT1220 IFU_en.pdf