510(k) Summary K120116

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Company: **Thermedical**
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Waltham, MA 02451-1036
United States of America

OCT 1 2012

FDA Establishment #: not yet assigned

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Proprietary: Thermedical SERF Ablation System and Accessories

Common: System, Ablation, Radio-frequency and Accessories

Classification: General and Plastic Surgery, GEI, 21 CFR 878.4400

Date Prepared: September 05, 2012

Indications for Use of the SERF™ System

The SERF Ablation System is intended for the coagulation and ablation of soft tissue during percutaneous, laparoscopic and intraoperative surgical procedures.

Predicate Devices

The Thermedical SERF Ablation System is substantially equivalent to the following currently marketed devices:

- AngioDynamics / RITA Model 1500 Electrosurgical RF Generator - Class II - 21CFR878.4400, which has been the subject of a cleared 510(k) with FDA log number K993944, K021329 and others.
- Covidien / ValleyLab Cool-Tip RF Generator, Cool-Tip RF System and Accessories - Class II - 21CFR878.4400, which has been the subject of a cleared 510(k) with FDA log number K984552, K052796 and K053290.

Technological Characteristics

The SERF Ablation System and SERF Ablation Needle provide heat to unwanted tissue targeted for ablation and thermal necrosis. The SERF System has these main components:

1. SERF Ablation System console which houses the RF generators, fluid pump, and system user interface. The system is designed to comply with Electrical Safety (IEC60601-1), Electromagnetic Compatibility (IEC60601-1-2), and Particular Requirements for the Safety of High Frequency Surgical Equipment (IEC60601-2-2). Product testing was conducted to evaluate conformance to product specifications. Software is validated.

2. System user interface, an alphanumeric display for menus and messages and a control panel which displays the set-point of each parameter of the therapy.
3. SERF Ablation Needle, a single-use, sterile device intended to penetrate tissue to locate the point of therapy initiation based on visual guidance. The SERF Needle is electrically connected to the system and delivers RF energy and warm saline to the tissue through perforations in the shaft near the needle tip. All patient contacting materials are commonly used and have been tested for biocompatibility in this application.
4. A sterile single-use syringe for use with the SERF system is commercially available. The syringe mounts on the pump and delivers sterile saline through a fluid delivery tube to the Ablation Needle.
5. Return electrode pads and cables for use with the SERF System are commercially available. The SERF system is a monopolar electrosurgical device. The RF circuit is closed through a return path including the return electrode pads which are plugged into the SERF system.

The System is programmed for the desired power level, and procedure time by the operator. Saline infusion rate and target saline temperature are also programmed. The system controls power by monitoring the voltage and current.

Performance Testing

The SERF Ablation System and accessories have been extensively tested to demonstrate suitability for clinical use as follows:

- Bioburden and sterility testing of the manufactured needle
- Sterilization dose substantiation and process validation of the manufactured needle
- Environmental control and package shelf life validation of the sterilized, single-use needle
- Biocompatibility of the sterilized, needle against requirements of tissue contacting / communicating device
- Needle performance characterization and function tests of electrical impedance and fluid leak
- Software validation for software of Major concern level
- Electrical safety testing according to IEC 60601-1
- Electromagnetic compatibility testing according to IEC 60601-1-2
- High frequency surgical equipment safety testing according to IEC 60601-2-2
- System console performance characterization and function tests of fluid flow rate, thermometry accuracy, pump response, power display accuracy, tipping force, and system alarm thresholds.
- Animal studies of ablation lesions performed at academic labs:

  1) *in-vivo* study of ablation lesions under different system control settings,

  2) chronic study of lesion pathology,

  3) explanted tissue study of SERF system ablation compared with two predicate systems, and

4) thermal rise study of return electrode pads.

- Non-significant risk human study of thermal rise of return electrode pads

Substantial Equivalence

The SERF Ablation System has the same intended use and indications for use as other previously 510(k) cleared RF ablation systems. The technological characteristics of the SERF Ablation System are also substantially similar to other previously cleared ablation systems. Although there are minor differences in technological characteristics between the SERF Ablation System and the predicates, these differences do not raise any new types of safety or effectiveness issues.

The SERF Ablation System is compared with the Covidien™ Cool-Tip™ and the AngioDynamics™ RITA™ predicate devices. Comparison of intended use, technological features, the therapy applicator, the control methodology, and the resulting ablative lesion demonstrates equivalence as confirmed by performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 1 2012

Thermedical
% Janice M. Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K120116
Trade/Device Name: SERF Ablation System and SERF Ablation Needle
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 14, 2012
Received: September 14, 2012

Dear Ms. Hogan:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K120116

Device Name: Saline-enhanced Radiofrequency (SERF) Ablation System and Accessories

Indications for Use:

The SERF Ablation System is intended for the coagulation and ablation of soft tissue during percutaneous, laparoscopic and intraoperative surgical procedures.

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

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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