K100786

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SECTION 5: 510(k) SUMMARY

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AUG 13 2010

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DATE PREPARED
April 26, 2010

TRADE OR PROPRIETARY NAME
MicroThermX® Microwave Ablation System (MTX-180 or MTX)

CLASSIFICATION/ NAME
Class II, (21CFR §878.4400), Electrosurgical cutting and coagulation device and accessories
Product Code- NEY

PREDICATE DEVICES
MicroThermX®-100 Microwave Ablation System (MTX-100) (K081042)
Valleylab VivaWave Microwave Ablation System (K053535)
Vivant Medical VivaTip Microwave Ablation Probe and Accessories (K032702)

DEVICE DESCRIPTION

The MicroThermX Microwave Ablation System (MTX-180 or MTX) delivers 915 MHz microwave energy for coagulation (ablation) of soft tissue. The delivery of microwave energy is controlled by time and power parameters set by the operator. The operator can select up to 3 applicators to ablate target tissue.

The MTX-180 consists of a mobile cart with generator and closed-circuit antenna cooling system, microwave antennas, and an optional temperature sensor.

The mobile generator is comprised of a computer, microwave generator, and thermistor-based temperature monitoring system. The operator interface is via the touchscreen monitor of the mobile generator.

The cooling system consists of a bag of sterile isotonic saline (not supplied by BSD); peristaltic pump; cooling circuit tubing and connectors; and fluid pathway channels within the antenna.

The MTX-180 is designed to:
- Deliver controlled microwave energy to induce coagulation of soft tissue;
- Provide repeatable ablation zone geometries for a given set of ablation parameters (repeatability demonstrated in *ex-vivo* studies performed in non-perfused animal tissue);
- Be used in an intraoperative or minimally invasive percutaneous procedure;
- Utilize a single SynchroWave antenna or synchronous operation of 2 or 3 antennas during a single procedure to induce larger zones of ablation.; and
- Utilize an optional sensor to monitor the temperature of non-target tissue during a procedure.

INTENDED USE

The MicroThermX® Microwave Ablation System (MTX) delivers microwave energy for coagulation (ablation) of soft tissue. The system is not intended for use in cardiac procedures. The SynchroWave antennas may be used in open surgical as well as percutaneous ablation procedures. An optional temperature sensor may be used to monitor tissue temperatures.

TECHNOLOGICAL COMPARISON

The modified device has the identical intended use and employs the same fundamental technology as the predicate devices.

The proposed design, material, and labeling changes that triggered the submission of this notification consist of changes in design: maximum total power output increased to 180 Watts; maximum power delivered to each antenna increased to 60W; number of antennas decreased from 4 to 3; cooling circuit added to cool antenna; reusable non-sterile temperature sensors replaced by sterile, pre-calibrated single-use temperature sensors; material changes (shaft material was changed when additional markers on antenna shaft were added to facilitate identification of insertion depth); software modifications to accommodate hardware changes); and labeling modifications to accommodate hardware changes and for clarity.

PERFORMANCE TESTING

Verification and Validation Studies were conducted to evaluate the equivalence of the new device to the predicate device, or conformance with relevant standards. Testing performed included evaluations to determine conformance with:

- UL 60601-1:2003 R6.03, *Medical Electronic Equipment: General requirements for basic safety and essential performance*
- IEC 60601:1988+A1:1991+A2:1995, *Medical Electronic Equipment: Particular requirements for Safety of Microwave Therapy Equipment*
- IEC 60601-1-2 (ed 2.1), *Medical Electronic Equipment: General requirements for basic safety and essential performance*
- IEC 60601-1-4, *Medical Electronic Equipment: Programmable Electrical Medical Systems*
- IEC 60601-2-2 (ed 4), *Particular Requirements for the Safety of High Frequency Surgical Equipment*
- IEC 60601-2-6 (ed.1), *Medical Electronic Equipment: Particular requirements for Safety of Microwave Therapy Equipment*
- CISPR 11 (2007), *Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radiofrequency Equipment*
- Internal safety and performance requirements for:
  - Software control of delivered power
  - Alarms and Shut-offs;
  - Temperature of applied parts
  - Cooling circuit function
  - Ablation zone sizes
  - Accuracy of temperature measurement by TempSure Temperature Sensors
  - Usability

The results of all testing performed demonstrated conformance with applicable, external standards or internal requirements and/ or equivalence with the predicate device.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

Based on the results of Verification and Validation Studies, BSD concludes that the modified devices are as safe and effective as, and perform as well as, or better than, the predicate devices.

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

AUG 13 2010

BSD Medical Corporation
% Phil Triolo and Associates LC
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148 S. 1200 East
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Re: K100786
Trade/Device Name: MicroThermX® Microwave Ablation System (MTX-180 or MTX)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY
Dated: August 06, 2010
Received: August 09, 2010

Dear Dr. Triolo:

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

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K100786

Device Name:

MicroThermX Microwave Ablation System

Indications for Use:

The MicroThermX Microwave Ablation System (MTX) delivers microwave energy for coagulation (ablation) of soft tissue. The system is not intended for use in cardiac procedures. The SynchroWave antennas may be used in open surgical as well as percutaneous ablation procedures. An optional temperature sensor may be used to monitor tissue temperatures.

Prescription Use X 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Posted November 13, 2003)

510(k) Number K100786