6. 510(k) Summary

Submitter Information

A. Company Name: Baylis Medical Company Inc.

B. Company Address: 2645 Matheson Blvd. East
Mississauga, Ontario L4W 5S4
Canada

C. Company Phone: (905) 602-4875; ext 252

D. Company Facsimile: (905) 602-5671

E. Contact Person: Meghal Khakhar

F. Summary Prepared on: March 7, 2011

Device Identification

A. Device Trade Name: OsteoCool™ RF Ablation System

B. Device Common Name: Electrosurgical cutting and coagulation device and accessories

C. Classification Name: Electrosurgical cutting and coagulation device and accessories, 21CFR 878.4400

D. Device Class: Class II

E. Device Code: GEI

Identification of Predicate Devices

Predicate Devices: OsteoCool™ RF Ablation System

Proposed Device	Predicate Device	Manufacturer	510(k) No.
OsteoCool™ RF Ablation System	RITA® System	RITA Medical Systems Inc.	K040989
	Ablation Generator System, and Ablation Instrument	DFine Inc.	K091310

Intended Use

The OsteoCool™ RF Ablation System is intended for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body in patients who have failed or are not candidates for standard pain therapy.

Device Description

The OsteoCool™ RF Ablation System includes the following components:

1. OsteoCool™ RF Ablation Kit consisting of:
    a. OsteoCool™ Probe
    b. OsteoCool™ Introducer
    c. Tube Kit
2. Pain Management Pump Unit & Pump Connector Cable
3. Baylis Pain Management Generator-TD
4. DuoCool™ Connector Cable

The OsteoCool™ RF Ablation System is designed to deliver controlled radiofrequency (RF) energy in a bipolar manner with a cooling mechanism. The Baylis Pain Management Generator-TD operates together with the OsteoCool™ Probe to deliver the RF energy. The Pump Connector Cable connects the Pump Unit to the Baylis Pain Management Generator-TD, which powers and controls the pump speed for delivery of cooling fluid during the procedure. The DuoCool™ Connector Cable connects the OsteoCool™ Probe to the Baylis Pain Management Generator-TD to transmit RF current and thermocouple signals to and from the electrodes of the probe.

The OsteoCool™ Probe is a single-use device that is inserted through the OsteoCool™ Introducer to the target site. The introducer is used for skin penetration and facilitates the navigation and accurate placement of the probe at the target site. The Tube Kit is used with the Pump Unit to circulate water internally to cool the probe while it delivers RF energy. The OsteoCool™ Probe includes a thermocouple to monitor and control the tissue temperature throughout the procedure.

Substantial Equivalence

The OsteoCool™ RF Ablation System is determined to be substantially equivalent to the predicate devices with respect to intended use, technological characteristics, and principles of operation.

The OsteoCool™ RF Ablation System and predicate devices share the following technological aspects:

- Principle of operation: Radiofrequency energy
- Mechanism of action: Cellular necrosis through thermal coagulation
- Feedback mechanism: Temperature-controlled
- Environment: Sterile
- User: Physicians familiar with RF lesion techniques
- Anatomical site of use: Bone

The proposed device is determined to be substantially equivalent to the predicate devices based on the results of performance tests listed below:

i) Biocompatibility Testing

The OsteoCool™ Probe and Introducer meet the requirements of the following biocompatibility tests:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Systemic Toxicity (Acute)

ii) Mechanical Testing

The OsteoCool™ Probe can withstand the following mechanical stresses without failure:

- A 40N or 15N steady pull test (as required by the joint)
- A 0.64J impulse test
- Pressurization of 200psi
- Cord Anchorage test over 100 or 200 cycles (as required by joint)

The OsteoCool™ Introducer can withstand the following mechanical stress without failure:

- 200N of force without failure.

The DuoCool™ Connector Cable can withstand the following mechanical stresses without failure:

- A 40N or 15N steady pull test (as required by the joint)
- A 0.64J impulse test
- Cord Anchorage test over 5000 cycles

iii) Electrical Testing

The OsteoCool™ Probe and DuoCool™ Connector Cable were subjected to and passed the requirements of the following electrical tests:

- High frequency leakage current
- High frequency dielectric strength at 1.2 times rated voltage ($160V_{rms}$) at 460 kHz
- Mains frequency dielectric strength of 1000V greater than rated voltage (160 V_{rms}) at 60 Hz

iv) Thermocouple Testing

The OsteoCool™ Probe was tested to establish the accuracy of the thermocouple measurements.

v) Bench Testing

Bench testing was conducted to examine the ability of the OsteoCool™ Probe to form reproducible lesions of consistent size and shape.

vi) In-vivo Animal Testing

The safety and efficacy of the OsteoCool™ RF Ablation System in ablating bone tumors, including those in the vertebral body has been validated in animal studies.

vii) Human Cadaver Testing

Testing was conducted to demonstrate the OsteoCool™ RF Ablation System's ability to successfully deliver RF energy in osteoporotic human cadaver vertebrae.

viii) Other Validation Testing

The following additional validation tests were performed on the OsteoCool™ Probe:

- Rough Handling
- Visualization
- Connectivity

The OsteoCool™ RF Ablation System is determined to be substantially equivalent to the predicate devices based on the performance tests described above. The technological differences between the proposed and predicate devices do not raise any new concerns of safety or effectiveness.

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

MAR 13 2012

Baylis Medical Co., Inc.
% Ms. Meghal Khakhar
2645 Matheson Blvd. E
Mississauga, Ontario
Canada L4W 5S4

Re: K111523
Trade/Device Name: OsteoCool™ RF Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 7, 2012
Received: March 8, 2012

Dear Ms. Khakhar:

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

K111523

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Indications for Use

510(k) Number (if known):

Device Name: OsteoCool™ RF Ablation System

Indications for Use:

The OsteoCool™ RF Ablation System is intended for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body in patients who have failed or are not candidates for standard pain therapy.

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

510(k) Number K111523