DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 16, 2015

Baylis Medical Company Incorporated
Meghal Khakhar
Director, Regulatory & Scientific Affairs
2645 Matheson Boulevard East
Mississauga, Ontario L4W 5S4
Canada

Re: K142480
Trade/Device Name: OsteoCool® V-2 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: May 7, 2015
Received: May 8, 2015

Dear 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 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" (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 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,

Binita S. Ashar -S

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

510(k) Number (if known): K142480

Device Name: OsteoCool® V-2 RF Ablation System

Indications for Use:

The OsteoCool® V-2 RF Ablation System is intended for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.

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)

7. 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

D. *Company Facsimile*: (905) 602-5671

E. *Contact Person*: Meghal Khakhar, Director of Regulatory & Scientific Affairs

F. *Summary Prepared on*: 09-Jun-2015

Device Identification

A. *Device Trade Name*: OsteoCool® V-2 RF Ablation System

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

C. *Classification Name*: CFR 878.4400 - Electrosurgical cutting and coagulation device and accessories

D. *Product Code*: GEI

E. *Device Class*: Class II

Identification of Predicate Device

Predicate Device

Predicate Device	Manufacturer	510(k)
Ablation Generator System, and Ablation Instrument	DFine Inc.	K091310

Reference Device

Reference Device	Manufacturer	510(k)
OsteoCool RF Ablation System	Baylis Medical Company Inc.	K111523

Indications for Use

The OsteoCool® V-2 RF Ablation System is intended for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.

Device Description

The OsteoCool V-2 RF Ablation System represents an upgrade to the cleared OsteoCool RF Ablation System (K111523) for the addition of a secondary system thermocouple to enable temperature monitoring around thermal ablation zones.

The OsteoCool V-2 RF Ablation System includes the following components:

1. OsteoCool RF Ablation Kit (OsteoCool Probe, OsteoCool Introducer, and Tube Kit)
2. Pain Management Pump Unit & Pump Connector Cable
3. Baylis Pain Management Generator-TD
4. DuoCool™ Y-Connector Cable With TC
5. Thermocouple Monitor
6. Thermocouple Monitor Box

The OsteoCool V-2 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 (PMG-TD) operates together with the OsteoCool Probe to deliver the RF energy to the target ablation site. The OsteoCool Introducer provides a path for the OsteoCool Probe to its target site. The Tube Kit is used with the Pain Management Pump Unit to circulate water internally through the OsteoCool Probe during RF energy delivery. The Pump Connector Cable connects the Pain Management Pump Unit to the PMG-TD, which powers and controls the pump speed. The DuoCool Y-Connector Cable With TC connects the OsteoCool Probe and Thermocouple Monitor to the PMG-TD. The Thermocouple Monitor Box is battery operated and connects to a port on the PMG-TD to display the temperature detected by the Thermocouple Monitor.

Comparison to Predicate Device

The OsteoCool V-2 RF Ablation System and predicate system by DFine Inc. share the same intended use and fundamental scientific technology, including principles of operation and mechanism of action. Differences in design and technological characteristics between the proposed and predicate devices do not raise any new concerns of safety and effectiveness.

A comparison of the intended use/indications for use and technological characteristics is provided in the table below.

Note: This document uses the term "substantial equivalence" as defined in 21 CFR 807.87 and not as defined in Title 35 of the U.S. Code. Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, ". . . a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without premarket approval or reclassification. The determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42.520 et seg. (1977).

Comparison of Proposed and Predicate Device

	ABLATION GENERATOR SYSTEM, AND ABLATION INSTRUMENT (K091310)	**OSTEOCOOL V-2 RF ABLATION SYSTEM (Proposed)**	**Identical / Substantially Equivalent**
Manufacturer	DFine Inc.	Baylis Medical Company Inc.	N/A
510(k) #	K091310	K142480	N/A
Class	II	II	YES/YES
Product Code	GEI, 878.4400	GEI, 878.4400	YES/YES
Indications for Use	For palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.	For palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.	YES/YES
User	Physicians familiar with RF lesion techniques	Physicians familiar with RF lesion techniques	YES/YES
Anatomical site of use	Bone	Bone	YES/YES
Access method	Percutaneous	Percutaneous	YES/YES
Energy type	Radiofrequency Energy (RF)	Radiofrequency Energy	YES/YES

	ABLATION GENERATOR SYSTEM, AND ABLATION INSTRUMENT (K091310)	**OSTEOCOOL V-2 RF ABLATION SYSTEM (Proposed)**	**Identical / Substantially Equivalent**
Principle of Operation	Operator controlled; RF delivered from compatible generator via connector cable	Operator controlled; RF delivered from compatible generator via connector cable	YES/YES
Mechanism of action	Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	YES/YES
Maximum power output for RF ablation in bone	25W	25W	YES/YES
Ablation probe configuration	Bipolar	Bipolar	YES/YES
Ablation probe dimensions	Shaft length= 16.5 cm Max OD= 3.0 mm RF active electrode length= up to 10 mm *(Active electrode dimension refers to output portion of electrode.)*	Shaft length= 21.5 cm Active tip OD= 1.5 mm RF active electrode length= up to 10 mm *(Active electrode dimension refers to output portion of electrode.)*	NO/YES
Number of system thermocouples	Two	Two	YES/YES
Location of distal thermocouple	5 or 10 mm from insulation tip depending on model	5 or 10 mm from centre of active tip depending on model	YES/YES
Location of proximal thermocouple	10 or 15 mm from insulation tip depending on model	Can be placed at 10 or 15 mm from centre of active tip depending on model	NO/YES

	ABLATION GENERATOR SYSTEM, AND ABLATION INSTRUMENT (K091310)	**OSTEOCOOL V-2 RF ABLATION SYSTEM (Proposed)**	**Identical / Substantially Equivalent**
Expected ablation zone propagation	As per DFine Inc. system IFU: -50°C on the probe at the 5mm TC represents an ablation zone of approximately 10mm long -50°C on the probe at the 10mm TC represents an ablation zone of approximately 20mm long -50°C on the probe at the 15mm TC represents an ablation zone of approximately 30mm long	-When proximal TC is placed at 5mm from the centre of the active tip, this represents an ablation zone of approximately 10mm long -When proximal TC is placed at 10mm from the centre of the active tip, this represents an ablation zone of approximately 20 mm long -When proximal TC is placed at 15mm from the centre of the active tip, this represents an ablation zone of approximately 30mm long	YES/YES
Frequency/Waveforms/Modulation	480kHz Sinusoidal	460kHz Sinusoidal	NO/YES
Rate of temperature rise in sample tissues	Controlled by RF generator energy output mechanism	Controlled by RF generator energy output mechanism	NO/YES
Conductive fluid used and flow rate	N/A-no conductive fluid is passed to patient	N/A-no conductive fluid is passed to patient (Internally cooled)	YES/YES
Feedback mechanism	Temperature-controlled	Temperature-controlled	YES/YES

	ABLATION GENERATOR SYSTEM, AND ABLATION INSTRUMENT (K091310)	**OSTEOCOOL V-2 RF ABLATION SYSTEM (Proposed)**	**Identical / Substantially Equivalent**
System components	-Ablation Instrument (including thermocouples) -Ablation RF Generator -AE Cable (for connection of generator to ablation instrument)	-OsteoCool RF Ablation Kit (Probe, Introducer, and Tube Kit) -Baylis Pain Management Generator-TD -DuoCool Y-Connector Cable With TC -Pain Management Pump Unit & Pump Connector Cable -Thermocouple Monitor -Thermocouple Monitor Box	NO/YES

The results of verification and validation testing support the safe and effective use of the proposed device for its intended use and its substantial equivalence determination to the predicate device.

Performance Testing

The following performance data were provided in support of the substantial equivalence determination:

Mechanical testing
Pull test
Impulse test

Electrical testing:
Electrical verification was conducted to ensure that the OsteoCool Thermocouple Monitor (OST) meets the electrical requirements of IEC 60601-1:2005 and IEC 60601-2-2:2009 after 0 and 4 years of aging.

Temperature Testing:
Temperature accuracy testing

Bench Top Validation Testing:

Ex-vivo Bovine Liver Testing:
Testing was conducted to demonstrate:
- Ablation probe response curves
- Thermocouple monitor response curves
- Comparison of lesion sizes

- Thermal profile and lesion boundaries

Human Cadaver Vertebrae Testing:
Testing was conducted to demonstrate:

- ablation volume
- thermal imaging
- comparison of ablation volumes with predicate

Conclusions

The OsteoCool V-2 RF Ablation System and the predicate device by DFine Inc. share the same intended use and fundamental scientific technology, including principles of operation and mechanism of action. Differences in design and technological characteristics between the proposed and predicate devices do not raise any new concerns of safety and effectiveness. The results of verification and validation support the safety and effectiveness of the proposed device for its intended use and its substantial equivalence determination to the predicate device.