DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 24, 2015

Baylis Medical Company Inc.
Meghal Khakhar
Director, Regulatory & Scientific Affairs/ Project Leader Regulatory Affairs
2645 Matheson Blvd. East
Mississauga, L4W 5S4 CA

Re: K152057
Trade/Device Name: Osteocool V-3 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: November 2, 2015
Received: November 3, 2015

Dear Meghal Khakhar:

This letter corrects our substantial equivalent letter of November 24, 2015.

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" (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 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,

Joshua C. Nipper -S

For 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152057

Device Name
OsteoCool® V-3 RF Ablation System

Indications for Use *(Describe)*
The OsteoCool® V-3 RF Ablation System is intended for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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*: 23-Jul-2015

Device Identification

A. *Device Trade Name*: OsteoCool® V-3 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

Table 7.1: Predicate Device

Predicate Device	Manufacturer	510(k)
OsteoCool V-2 RF Ablation System	Baylis Medical Company Inc.	K142480

Indications for Use

The OsteoCool® V-3 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-3 RF Ablation System includes the following components:

1. OsteoCool Radiofrequency Generator
2. OsteoCool RF Ablation Kit:
    i. OsteoCool RF Ablation Probe
    ii. OsteoCool Tube Kit
3. OsteoCool Thermocouple Kit:
    i. Osteocool Thermocouple Monitor
    ii. Osteocool Thermocouple Monitor Introducer
4. Osteocool Peristaltic Pump & OsteoCool Pump Cable
5. OsteoCool Connector Hub
6. OsteoCool Footswitch
7. OsteoCool Cart

The OsteoCool V-3 RF Ablation System represents an upgrade to the predicate OsteoCool V-2 RF Ablation System (K142480). Modifications have been made to the predicate generator and pump unit for aesthetic changes and to provide increased user flexibility and convenience. Minor changes have also been made to other system components for increased user flexibility and convenience and to optimize existing features.

The OsteoCool V-3 RF Ablation System delivers controlled radiofrequency (RF) energy in a bipolar manner with a cooling mechanism to facilitate RF lesions in the vertebral body. The OsteoCool Radiofrequency (RF) Generator operates together with the OsteoCool RF Ablation Probe to deliver the RF energy to the target ablation site(s). The OsteoCool Tube Kit is used with the Osteocool Peristaltic Pump to circulate water internally through the OsteoCool RF Ablation Probe(s) during RF energy delivery. The OsteoCool Pump Cable connects the Osteocool Peristaltic Pump to the OsteoCool RF Generator, which controls the pump speed. The OsteoCool Connector Hub connects the OsteoCool RF Ablation Probe(s) and Osteocool Thermocouple Monitor(s) to the OsteoCool RF Generator. The Osteocool Thermocouple Monitor is used with the OsteoCool Thermocouple Monitor Introducer and enables temperature monitoring around the thermal ablation zones during procedures. The OsteoCool RF Generator can be used with the optional OsteoCool Footswitch. The OsteoCool RF Generator and Peristaltic Pump are mounted on the OsteoCool Cart during use.

Comparison to Predicate Device

The indications for use of the OsteoCool V-3 RF Ablation System are identical to that of the predicate OsteoCool V-2 RF Ablation System (K142480). The proposed and predicate devices also share the same fundamental scientific technology, including principles of operation and mechanism of action (Table 7.2). Differences in design and technological characteristics between the proposed and predicate devices do not raise any new types of questions of safety and effectiveness. The results of verification and validation testing provide reasonable assurance of substantial equivalence of the OsteoCool V-3 RF Ablation System with the predicate device.

Table 7.2: Comparison of Proposed and Predicate Devices

	OSTEOCOOL V-2 RF ABLATION SYSTEM (predicate)	**OSTEOCOOL V-3 RF ABLATION SYSTEM (proposed)**	**Identical / SE**
Manufacturer	Baylis Medical Company Inc.	Baylis Medical Company Inc.	YES/YES
510(K) #	K1422480	K152057	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	Radiofrequency Energy	YES/YES
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
Feedback mechanism	Temperature-controlled	Temperature-controlled	YES/YES

System components	-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	-OsteoCool RF Ablation Kit (Probe and Tube Kit) -OsteoCool Radiofrequency Generator -OsteoCool Thermocouple Kit (Thermocouple Monitor, Thermocouple Monitor Introducer) -OsteoCool Peristaltic Pump & Pump Cable -OsteoCool Connector Hub -OsteoCool Footswitch -OsteoCool Cart	NO/YES
Generator			
Name	Pain Management Generator – TD	OsteoCool Radiofrequency Generator	N/A
Maximum power output for RF ablation in bone	25W	25W	YES/YES
Frequency/ Waveforms/ Modulation	460kHz Sinusoidal	465 kHz Sinusoidal	NO/YES
Needle tract ablation parameters	*'Track Burn' Mode*	*'Retract' Mode*	NO/YES
Needle tract ablation parameters – Target temperature	N/A-Power setting is used	95 °C	
Needle tract ablation parameters – Cooling	No	No	
Needle tract ablation parameters – Additional patient connections required	No	No	
Needle tract ablation parameters – Same ablation probe used	Yes	Yes	
Needle tract ablation parameters – On-screen temperature display	Yes	Yes	
Needle tract ablation parameters – User controlled	Yes	Yes	
Needle tract ablation parameters – On-screen error messaging	Yes	Yes	
Display parameters	Real time temperature, impedance, and power	Real time temperature, impedance, and power	YES/YES
Probe recognition through EEPROM chip	No	Yes	NO/YES
Touchscreen	No	Yes	NO/YES
Used with OsteoCool Cart	No	Yes	NO/YES

Used with optional Footswitch		Yes	Yes	YES/YES
Environment		Supplied non-sterile; non-sterilizable	Supplied non-sterile; non-sterilizable	YES/YES
OsteoCool RF Ablation Kit				
Kit components		OsteoCool Probe, Introducer, Tube Kit	OsteoCool Probe, Tube Kit	NO/YES
Ablation probe configuration		Bipolar	Bipolar	YES/YES
Ablation probe dimension	Shaft diameter	17 Gauge	17 Gauge	NO/YES
	RF active electrode lengths	10 or 20mm	7, 10, or 20mm	
Ablation probe materials	Shaft, thermocouple	304 Stainless steel	304 Stainless steel	NO/YES
	Insulation	Polyethylene terephthalate (PET)	Polyimide	
	Radiopaque band	Platinum/10% Iridium	Platinum/10% Iridium	
EEPROM in connector		No	Yes	NO/YES
Tube kit clip (for pump attachment)		NO	Yes	NO/YES
Tube kit dimensions	Tubing length	140”	140”	YES/YES
	Burette capacity	70 mL	70 mL	
Tube kit materials	Tubing	Tygon	Tygon	NO/YES
	Burette, female luer cap, luer locks	Polycarbonate	Polycarbonate	
	Clip (for pump attachment)	N/A	Polycarbonate	
	Reinforcement crimp for tubing	N/A	Stainless steel	
Packaging		PETG thermoform tray sealed with coated Tyvek® lid	PETG thermoform tray sealed with coated Tyvek® lid	YES/YES
Sterilization		Ethylene oxide	Ethylene oxide	YES/YES
Sterility Assurance Level		10^{-6}	10^{-6}	YES/YES
Environment		Provided sterile; Single use	Provided sterile; Single use	YES/YES
OsteoCool Thermocouple Monitor				
Number of system thermocouples		Two	Two	YES/YES

Temperature display		OsteoCool Thermocouple Monitor Box	OsteoCool RF Generator	NO/YES
Dimen-sions	Shaft diameter	18 Gauge	28 Gauge	NO/YES
	Usable length	160 mm	200 mm	
Packaging		PETG thermoform tray sealed with coated Tyvek® lid	PETG thermoform tray sealed with coated Tyvek® lid	YES/YES
Sterilization		Ethylene oxide	Ethylene oxide	YES/YES
Sterility Assurance Level		10^{-6}	10^{-6}	YES/YES
Environment		Provided sterile; Single use	Provided sterile; Single use	YES/YES
OsteoCool Pump Unit & Pump Cable				
Number of pump heads		Two	Two	YES/YES
Control of pump speed by generator		Yes	Yes	YES/YES
Used with Tube Kit(s)		Yes	Yes	YES/YES
Safety switch		Yes	Yes	YES/YES
Used with OsteoCool Cart		No	Yes	NO/YES
Environment		Supplied non-sterile; non-sterilizable	Supplied non-sterile; non-sterilizable	YES/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

Performance testing was completed to demonstrate substantial equivalence of the OsteoCool V-3 RF Ablation System to the predicate OsteoCool V-2 RF Ablation System (K142480). The system components were subjected to the following verification and validation tests, as applicable:

Mechanical testing

Mechanical verification testing was conducted for the proposed OsteoCool V-3 RF Ablation System to ensure compliance with mechanical requirements of IEC 60601-1: 2005, IEC 60601-2-2: 2009, and Baylis self-enforced requirements.

Electrical testing

Electrical verification testing was conducted for the relevant components of the proposed OsteoCool V-3 RF Ablation System to ensure compliance with current electrical standard requirements.

Electromagnetic compatibility
Electromagnetic compatibility (EMC) testing has been completed for the applicable components of the proposed OsteoCool V-3 RF Ablation System. The results demonstrated compliance of the proposed system to current IEC 60601-1-2 standard requirements.

Biocompatibility
Biocompatibility verification was performed in accordance with requirements of ISO 10993-1 and FDA's modified ISO guidelines in accordance with FDA's blue book memorandum #G95-1 on biocompatibility

Thermocouple temperature accuracy
Verification testing demonstrated that the relevant components of the proposed OsteoCool V-3 RF Ablation system achieves accurate temperature measurements as per specified test requirements.

Usability
Testing was performed to verify and validate the usability requirements of the proposed OsteoCool V-3 RF Ablation System.

Software
FDA's "Guidance for the content of premarket submissions for software contained in Medical Devices" (May-2005) was used to determine the Level of Concern for the software in the OsteoCool V-3 RF Ablation System.

Bench-top validation testing
Ev-vivo Bovine Liver Testing:
Testing was conducted to demonstrate:
- Ablation probe 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

All test requirements were met as specified by applicable standards and the test protocols.

Conclusions

The OsteoCool V-3 RF Ablation System and the predicate OsteoCool V-2 RF Ablation System share the same indications for 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 types of questions of safety and effectiveness. The results of verification and validation testing support substantial equivalence of the OsteoCool V-3 RF Ablation System with its predicate device.