DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

January 31, 2017

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

Re: K161949
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: January 23, 2017
Received: January 24, 2017

Dear Meghal 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" (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,

Jennifer R. Stevenson -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)*
K161949

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.

• Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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*: 14-Jul-2016

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 Devices

Table 7.1: Predicate Devices

Predicate Device	Manufacturer	510(k)
OsteoCool V-3 RF Ablation System (Primary)	Baylis Medical Company Inc.	K152057 (Primary)
Uniblate Electrosurgical Device	AngioDynamics, Inc.	K080451

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.
- Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

Device Description

The current 510(k) submission is only for a modification to the indications for use of the cleared OsteoCool V-3 RF Ablation System (K152057). The subject device is identical in all other aspects to the cleared OsteoCool V-3 RF Ablation System (K152057).

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 delivers controlled radiofrequency (RF) energy in a bipolar manner with a cooling mechanism to facilitate RF lesions in target tissue. 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 Devices

The intended use of the subject device is substantially equivalent to those of the predicate devices. The indications for use of the subject device represents a modification to the primary predicate OsteoCool V-3 RF Ablation System (K152057) indications for use to enable use in all bones, including the vertebral body. The indications for use of the subject device is a subset of the predicate Uniblate Electrosurgical Device (K080451).

Except for the indications for use, the subject device is identical in all aspects to the primary predicate OsteoCool V-3 RF Ablation System (K152057). This includes the fundamental scientific technology, principles of operation and mechanism of action, and design and technological aspects (Table 7.2). The proposed modification to the indications for use does not impact any of these device characteristics.

The subject OsteoCool V-3 RF Ablation System and predicate Uniblate Electrosurgical Device (K080451) share the same fundamental scientific technology, including principles of operation and mechanism of action. They are substantially equivalent with respect to design and technological characteristics. The predicate Uniblate Electrosurgical device delivers RF energy in a monopolar configuration, with a retractable insulating sheath to expose a variable active electrode length. The subject OsteoCool RF Ablation Probe delivers RF energy in a bipolar manner, which eliminates the need for a grounding pad. The subject device includes different available electrodes of fixed active electrode lengths. The Uniblate predicate device provides local fluid delivery to the ablation site through an infusion channel, while the subject device integrates an internal cooling mechanism by internally circulating water through the electrode/probe during RF delivery. In addition, the compatible RF generator used with the Uniblate and OsteoCool probes differ primarily with respect to output power and default ablation temperature. Table 7.2 provides a detailed comparison of the predicate Uniblate and subject OsteoCool devices. Existing differences do not raise any new types of questions of safety and effectiveness.

The results of verification and validation testing provide reasonable assurance of the substantial equivalence of the subject OsteoCool V-3 RF Ablation System to the predicate devices.

Table 7.2: Comparison of Subject and Predicate Devices

	PREDICATE DEVICES		SUBJECT DEVICE	Identical / Substantially Equivalent (SE)
	OsteoCool V-3 RF Ablation System (K152057) (Primary Predicate)	**Uniblate Electrosurgical Device (K080451)**	**OsteoCool V-3 RF Ablation System**	
Class	II	II	II	YES/YES
Product Code	GEI, 878.4400	GEI, 878.4400	GEI, 878.4400	YES/YES
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.	The AngioDynamics Uniblate Electrosurgical Device is intended for coagulation and ablation of tissue during percutaneous, laparoscopic, and intraoperative surgical procedures such as partial or complete ablation of non-resectable liver lesions, osteoid osteoma, and palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.	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. • Coagulation and ablation of tissue in bone during surgical procedures including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.	NO/YES
User	Physicians familiar with RF lesion techniques	Physicians familiar with RF lesion techniques	Physicians familiar with RF lesion techniques	YES/YES
Anatomical site of use	Bone (Vertebral body)	Bone, Soft tissue	Bone	NO/YES
Access method	Percutaneous	Percutaneous, laparoscopic, intraoperative	Percutaneous	NO/YES
Energy type	Radiofrequency Energy	Radiofrequency Energy	Radiofrequency Energy	YES/YES
Principle of operation	Operator controlled; RF delivered from compatible RF generator	Operator controlled; RF delivered from compatible RF generator	Operator controlled; RF delivered from compatible RF generator	YES/YES

		PREDICATE DEVICES		SUBJECT DEVICE	Identical / Substantially Equivalent (SE)
		OsteoCool V-3 RF Ablation System (K152057) (Primary Predicate)	**Uniblate Electrosurgical Device (K080451)**	**OsteoCool V-3 RF Ablation System**	
Mechanism of action		Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	YES/YES
Rate of temperature rise in sample tissues		Controlled by RF generator energy output mechanism	Controlled by RF generator energy output mechanism	Controlled by RF generator energy output mechanism	YES/YES
Feedback mechanism		Temperature-controlled	Temperature-controlled	Temperature-controlled	YES/YES
Operating mode		Bipolar RF energy	Monopolar RF energy	Bipolar RF energy	NO/YES
Active electrode lengths		0.7, 1.0, 2.0 cm	1.0 to 3.0 cm (adjustable)	0.7, 1.0, 2.0 cm	NO/YES
Location of thermocouple on probe/electrode		0.5-1.0 mm from the probe distal tip	6-7 mm from the probe distal tip	0.5-1.0 mm from the probe distal tip	NO/YES
Active electrode material		Stainless steel	Stainless steel	Stainless steel	YES/YES
Electrode insulation material		Polyimide	Polyimide	Polyimide	YES/YES
Electrode/probe length(s)		16 cm	10, 15, 25 cm	16 cm	NO/YES
Electrode diameter		17 Gauge	17 Gauge	17 Gauge	YES/YES
Sterilization (Electrode)		EO, Single use	EO, Single use	EO, Single use	YES/YES
Compatible RF generator		OsteoCool Radiofrequency (RF) Generator	RITA Medical Systems 1500X Generator	OsteoCool Radiofrequency (RF) Generator	NO/YES
Generator Parameters	Output Power	40 W	250 W	40 W	NO/YES
	Maximum Voltage	130 V_{RMS}	135 V_{RMS}	130 V_{RMS}	NO/YES
	Output Frequency	465 kHz ± 3%	460 kHz ±5%	465 kHz ± 3%	NO/YES
	Maximum Current	1.0 A_{RMS}	6.0 A_{RMS}	1.0 A_{RMS}	NO/YES
	Default Ablation Temperature	70 °C	103 °C	70 °C	NO/YES
Other system components		Thermocouple monitor and introducer, peristaltic pump and tube kit, connector hub, footswitch	Peristaltic pump and infusion tubing, connector cable, grounding pad, footswitch	Thermocouple monitor and introducer, peristaltic pump and tube kit, connector hub, footswitch	NO/YES

Performance Testing

Performance testing has been completed to demonstrate substantial equivalence of the subject OsteoCool V-3 RF Ablation System to the predicate devices. The system components were subjected to the following verification and validation tests, as applicable:

Mechanical testing
Mechanical verification testing was conducted for the subject 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 subject OsteoCool V-3 RF Ablation System to ensure compliance with current electrical standard requirements.

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

Biocompatibility
Biocompatibility verification was performed for patient-contacting components of the OsteoCool V-3 RF Ablation System in accordance with current ISO 10993-1 requirements.

Thermocouple temperature accuracy
Verification testing demonstrated that the relevant components of the subject 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 subject OsteoCool V-3 RF Ablation System.

Software
The applicable software verification and validation was completed for the OsteoCool Radiofrequency Generator and Osteocool Peristaltic Pump based on a Major Level of Concern classification for the devices. 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 devices.

Comparative bench-top validation testing
Direct comparative bench top validation testing was completed to demonstrate the substantially equivalent ablation performance of the subject device and predicate Uniblate Electrosurgical Device (K080451). The soft tissue model consisted of fresh bovine liver placed in shell of bovine bone. For each test, temperature response curves showing temperature and power over time were generated from procedural data obtained from each respective RF generator. Following lesion formation, the tissue samples were cross-sectioned and lesion dimensions directly measured. The results demonstrated that the lesion dimensions achieved by the subject device are substantially equivalent to those obtained with the predicate device under the same test setup and conditions.

Clinical
An updated scientific literature review of the current scientific literature describing radiofrequency ablation (RFA) of metastatic bone tumors for pain palliation was completed. The literature search was performed for published clinical articles from 2007 to present. All scientific literature describing the use of RFA systems for ablation of metastatic bone tumors for pain palliation within this period that did not meet the predetermined exclusion criteria were included in the literature review. Based on the established criteria and assessment of the peer-reviewed literature, in conjunction with the literature review submitted in the predicate Uniblate device 510(k) K080451, the literature review results support the established use of RFA in patients with bone metastases for pain palliation.

Pyrogen testing
The OsteoCool RF Ablation Kit and OsteoCool Thermocouple Monitor Kit are supplied non-pyrogenic. LAL testing using the Kinetic Chromogenic method will be conducted on every lot to verify that devices are non-pyrogenic. The devices meet current FDA and USP pyrogen limit specifications.

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

Conclusions

The intended use of the subject OsteoCool V-3 RF Ablation System is substantially equivalent to the predicate devices. The subject and predicate devices share the same fundamental scientific technology, including principles of operation and mechanism of action. Differences in design and technological characteristics between the subject device and predicate Uniblate Electrosurgical Device (K080451) do not raise any new types of questions of safety and effectiveness. The results of verification and validation testing support the substantial equivalence of the subject OsteoCool V-3 RF Ablation System to the predicate devices.