January 15, 2019

Medtronic Sofamor Danek USA, Inc.
Ms. Laveeda Leflore
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K182497
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: December 14, 2018
Received: December 17, 2018

Dear Ms. Leflore:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182497

Device Name
OsteoCool™ RF Ablation System

Indications for Use *(Describe)*
The OsteoCool™ 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.
- Ablation of benign bone tumors such as osteoid osteoma.

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.

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K182497

510(k) Summary
Medtronic Sofamor Danek USA, Inc.

January 14, 2019

Submitter	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact	Laveeda Leflore Regulatory Affairs Specialist Direct Telephone: 901-399-2953 Jeff Sprague Sr. Regulatory Affairs Program Manager Direct Telephone: 901-344-1326
Date Prepared	January 14, 2019
Common Name	OsteoCool™ RF Ablation System
Regulatory Class	Class II
Regulation Number	21 CFR 878.4400
Regulation Name and Device	Electrosurgical cutting and coagulation device and accessories
Product Classification Code	GEI
Predicate Devices	OsteoCool® V-3 RF Ablation System K161949 (S.E. 01/24/2017) – primary predicate Uniblate Electrosurgical Device K080451 (S.E. 07/03/2008) The predicate devices have not been subject to a design related recall.

Description of Device

The current 510(k) submission is only for a modification to the indications for use of the cleared OsteoCool™ RF Ablation System (K161949). The subject device is identical in all other aspects cleared in OsteoCool® V-3 RF Ablation System (K161949, S.E. 01/24/2017).

The OsteoCool™ 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 Cart

The OsteoCool™ 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.

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.

▪ 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.

▪ Ablation of benign bone tumors such as osteoid osteoma.

Comparison to Predicate Devices

The indications for use of the subject device represents a modification to the indications for use of the primary predicate OsteoCool V- 3 RF Ablation System (K161949, S.E. 01/24/2017) to enable ablation of benign bone tumors such as osteoid osteoma. The proposed modification to the indications for use does not impact any of these device characteristics because the fundamental scientific technology, principles of operation and mechanism of action, and design and technological aspects is substantially equivalent.

In order to demonstrate substantial equivalence, previously FDA cleared 510(k)s OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017) K161949 (S.E. 01/24/2017) and Uniblate Electrosurgical Device K080451 (S.E. 07/03/2008), which are listed below, in Table 12-1, for the OsteoCool V-3 RF Ablation System are being used as the predicates.

Table 5-1: Comparison Table of Predicate and Subject Devices

	PREDICATE	**PREDICATE**	**SUBJECT DEVICE**
	OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017)	**Uniblate Electrosurgical Device K080451 (S.E. 07/03/2008)**	**OsteoCool™ RF Ablation System**
Class	II	II	Identical
Product Code	GEI, 878.4400	GEI, 878.4400	Identical

	PREDICATE	PREDICATE	SUBJECT DEVICE
	OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017)	**Uniblate Electrosurgical Device K080451 (S.E. 07/03/2008)**	**OsteoCool™ RF Ablation System**
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 during surgical procedures such as palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.	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™ 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 during surgical procedures such as palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy. • Ablation of benign bone tumors such as osteoid osteoma.
User	Physicians familiar with RF lesion techniques	Physicians familiar with RF lesion techniques	Identical

	PREDICATE	PREDICATE	SUBJECT DEVICE
	OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017)	**Uniblate Electrosurgical Device K080451 (S.E. 07/03/2008)**	**OsteoCool™ RF Ablation System**
Anatomical site of use	Bone	Bone, Soft tissue	Identical to OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017)
Access method	Percutaneous	Percutaneous, laparoscopic, intraoperative	Identical to OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017)
Energy type	Radiofrequency Energy	Radiofrequency Energy	Identical
Principle of operation	Operator controlled; RF delivered from compatible RF generator	Operator controlled; RF delivered from compatible RF generator	Identical
Mechanism of action	Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	Identical
Rate of temperature rise in sample tissues	Controlled by RF generator energy output mechanism	Controlled by RF generator energy output mechanism	Identical
Feedback mechanism	Temperature-controlled	Temperature-controlled	Identical
Operating mode	Bipolar RF energy	Monopolar RF energy	Identical to OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017).
Active electrode lengths	7, 10, 20 mm	1.0 to 3.0 cm (adjustable)	7, 10, 15, 20 mm (within cleared range of predicate K161949)
Active electrode material	Stainless steel	Stainless steel	Identical
Electrode insulation material	Polyimide	Polyimide	Identical

	PREDICATE	PREDICATE	SUBJECT DEVICE
	OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017)	**Uniblate Electrosurgical Device K080451 (S.E. 07/03/2008)**	**OsteoCool™ RF Ablation System**
Available electrode length(s)	16 cm	10, 15, 25 cm	Identical to OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017).
Electrode diameter	17 Gauge	17 Gauge	Identical
Sterilization (Electrode)	EO, Single use	EO, Single use	Identical
Compatible RF generator	OsteoCool Radiofrequency (RF) Generator	RITA Medical Systems 1500X Generator	Identical to OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017).
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	Similar to OsteoCool V-3 RF Ablation System (K161949, S.E. 01/24/2017). Subject OsteoCool™ RF Ablation System does not include the optional footswitch.

Performance Testing

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

Mechanical testing

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

Electrical testing

Electrical verification testing was conducted for the relevant components of the subject OsteoCool™ 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™ 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™ 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™ 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™ 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, S.E. 07/03/2008). 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.

Impedance Testing

The purpose of this study was to evaluate the performance of OsteoCool in dry (low electrolyte) fresh bovine bone that contained cartilaginous tissue and periosteum, an environment similar to osteoid osteomas. Impedance Testing with dry bovine bone verified

that the OsteoCool™ RF Ablation Probe can be used to adequately perform ablations in dry bone, as often seen in Osteoid Osteoma.

Impedance tests in patients with osteoid osteoma confirmed that the patient data is similar to the bench testing result with dry bovine bone tissue and the subject device is safe and effective for the intended use. Multiple mitigation measures are adopted to reduce risks related associated with abrupt impedance rise or impedance higher than the preset threshold value.

Clinical

The purpose of the literature review provided here is to demonstrate the performance and safety of radiofrequency ablation (RFA) to treat Osteoid Osteoma (OO). Performance was assessed using reported outcomes such as technical success, clinical success, changes in pain, and repeat RFA procedures. Safety was conservatively assessed by review of all reported complications regardless of time of onset or reported relatedness to the device/therapy/or procedure. Medtronic's examined both the published use of RFA in OO regardless of manufacturer and irrespective of patient demographic or tumor location and patient outcomes to determine if any new patient risks are created. Medtronic maintains that the potential benefits provided by these devices outweigh the potential risks.

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

Based on the data provided in the premarket notification, the intended use of the subject OsteoCool™ 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, S.E. 07/03/2008) 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™ RF Ablation System to the predicate devices.