February 28, 2024

Medtronic Sofamor Danek USA Inc.
Denise Gaston
Sr. Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K233830
Trade/Device Name: OsteoCool™ 2.0 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 30, 2023
Received: December 1, 2023

Dear Denise Gaston:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.02.28 08:25:14 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices

Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233830

Device Name

OsteoCool™ 2.0 RF Ablation System

Indications for Use *(Describe)*

• 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.

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.

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

February 27, 2024

Submitter	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 498-2697
Contact	Jeff Sprague Sr. Prin. Regulatory Affairs Lead Direct Telephone: 901-498-2697 Email: jeffrey.a.sprague@medtronic.com **Or** Denise Gaston Sr. Regulatory Affairs Specialist Direct Telephone: 416-576-8749 Email: denise.gaston@medtronic.com
Date Prepared	February 27, 2024
Common Name	OsteoCool™ 2.0 RF Ablation System
Regulatory Class **Regulation Number** **Regulation Name and Device** **Product Classification Code**	Class II 21 CFR 878.4400 Electrosurgical cutting and coagulation device and accessories GEI
Predicate Devices	OsteoCool™ RF Ablation System K182497 (S.E. 12/17/2018) – primary predicate The predicate devices have not been subject to a design related recall.
Description of Device	The current 510(k) submission is for a line extension to the cleared OsteoCool™ RF Ablation System (K182497 S.E. 12/17/2018). The subject OsteoCool™ 2.0 RF Ablation System includes the following hardware components: 1. OsteoCool™ 2.0 Radiofrequency Generator 2. OsteoCool™ 2.0 Peristaltic Pump & Pump Cable 3. OsteoCool™ 2.0 Connector Hub 4. OsteoCool™ 2.0 Cart The OsteoCool™ 2.0 RF Ablation System line extension includes the following commercially available sterile disposables that remain unchanged from the OsteoCool™ RF Ablation System K182497 (S.E. 12/17/2018):

Description of Device	5. OsteoCool™ RF Ablation Probe with Tube Kit 6. OsteoCool™ Independent Thermocouple with Introducer Kit: The OsteoCool™ 2.0 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™ 2.0 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™ 2.0 Peristaltic Pump to circulate water internally through the OsteoCool™ RF Ablation Probe(s) during RF energy delivery. The OsteoCool™ 2.0 Pump Cable connects the OsteoCool™ 2.0 Peristaltic Pump to the OsteoCool™ 2.0 RF Generator, which controls the pump flowrate. The OsteoCool™ 2.0 Connector Hub connects the OsteoCool RF Ablation Probe(s) and OsteoCool™ Thermocouple (s) to the OsteoCool™ 2.0 RF Generator. The OsteoCool™ Thermocouple Monitor is used with the OsteoCool™ Thermocouple Introducer and enables temperature monitoring around the thermal ablation zones during procedures.
Indications for Use:	The OsteoCool™ 2.0 RF Ablation System is indicated 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 of Technological Characteristics with the Predicate Device	The intended use of the subject device is substantially equivalent to those of the predicate device. This includes the fundamental scientific technology, principles of operation and mechanism of action, and design

	and technological aspects.

Comparison Table of Subject and Predicate Devices:		
	OsteoCool™ 2.0 RF Ablation System **SUBJECT DEVICE**	***OsteoCool RF Ablation System*** **PREDICATE DEVICE**
510(k) Clearance	TBD	K182497 (S.E. 12/17/2018)
Regulation Number	21 CFR 878.4400	21 CFR 878.4400
Product Code	GEI	GEI
Product Class	Class II	Class II
Indication for Use	The OsteoCool™ 2.0 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.	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.
User	Physicians trained in the use of OsteoCool RF ablation system	Physicians trained in the use of OsteoCool RF ablation system
Anatomical Site of Use	Bone	Bone
Method of Access	Percutaneous	Percutaneous

TECHNICAL DETAILS - System		
FEATURE	***OsteoCool™ 2.0 RF Ablation System*** **SUBJECT DEVICE**	***OsteoCool RF Ablation System*** **PREDICATE DEVICE**
Energy Type	Radiofrequency	Radiofrequency
Principle of Operation	Radiofrequency energy delivered by operator from generator	Radiofrequency energy delivered by operator from generator
Mechanism of Action	Thermal coagulation necrosis	Thermal coagulation necrosis
Energy Delivery Control Mechanism	Temperature controlled	Temperature controlled
Probe Active Tip Size	7mm, 10mm, 15mm, 20mm	7mm, 10mm, 15mm, 20mm
Probe Outer Diameter	17Gauge	17Gauge
Probe length	16 cm	16 cm

Probe Electrodes Material	Stainless Steel	Stainless Steel
Probe Dielectric Materials	Polyimide	Polyimide
Electrode Sterilization	EtO, single use	EtO, single use
Compatible RF Generator	OsteoCool 2.0	OsteoCool
Number of independent thermocouples	4	2
Number of probes	4	2
Generator Power Output Channels	4	2
Generator Maximum Output Power	• 80 Watts total • 20 W/channel	• 40 Watts total • 20 W/channel
Generator Maximum Voltage	224 V_{RMS}	130 V_{RMS}
Generator Maximum Current	1.2 A_{RMS}	1.0 A_{RMS}
Generator Output Frequency	465.1 kHz	465.1 kHz
Default Ablation Temperature	70C (Gradual)	70C
	75C (Accelerated)	N/A
Cooling medium	Sterile water	Sterile water
System components	Pump OC02-100 Hub OC04-100	Pump OC02 Hub OC04
	Single Probe Kit 7 mm -OCP107	Single Probe Kit 7 mm -OCP107
	Single Probe Kit 10 mm -OCP110	Single Probe Kit 10 mm -OCP110
	Single Probe Kit 15 mm -OCP115	Single Probe Kit 15 mm - OCP115
	Single Probe Kit 20 mm -OCP120	Single Probe Kit 20 mm -OCP120
	Dual Probe Kit 7 mm x2 -OCP207	Dual Probe Kit 7 mm x2 -OCP207
	Dual Probe Kit 10 mm x2 -OCP210	Dual Probe Kit 10 mm x2 -OCP210
	Dual Probe Kit 15 mm x2 -OCP215	Dual Probe Kit 15 mm x2 -OCP215
	Dual Probe Kit 20 mm x2 -OCP220	Dual Probe Kit 20 mm x2 -OCP220
	RF Pump - OC02	RF Pump - OC02
	ITC 28G - OCN001	ITC 28G - OCN001

Performance Data	Bench top testing was performed to demonstrate substantial equivalence of the OsteoCool™ 2.0 RF Ablation System to the predicate device. The system components were subjected to the following verification and validation tests, as applicable: mechanical, electrical, biocompatibility, data integrity, temperature accuracy, cleaning, connectivity, and usability. Bench-top validation testing was performed for the OsteoCool™ 2.0 RF Ablation System using ex-vivo tissue and product usage in cadaveric bone as per the guidance. Lesion size (length and width) was measured during ex-vivo testing at the 50 degree C isotherm. Color change due to blood coagulation at elevated temperatures between thermally affected tissue and raw tissue was evaluated.
Conclusion	The subject and predicate devices share the same fundamental scientific technology, including principles of operation and mechanism of action. The subject OsteoCool™ 2.0 RF Ablation System has been shown through technological comparison and comparison testing to be substantially equivalent to the identified predicate system for the requested indications for use.