June 5, 2026

Medtronic Sofamor Danek USA, Inc.
Jeff Sprague
Sr. Principal, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K253656
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: May 7, 2026
Received: May 7, 2026

Dear Jeff Sprague:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2026.06.05 15:23:58 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253656

Please provide the device trade name(s).

OsteoCool™ 2.0 RF Ablation System

Please provide your Indications for Use below.

▪ 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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K253656
510(k) Summary
Medtronic Sofamor Danek USA, Inc.

Submitter	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, Tennessee 38132
Contact	Jeff Sprague Sr. Principal, Regulatory Affairs Direct Telephone: 901-498-2697 Email: jeffrey.a.sprague@medtronic.com
Date Prepared	November 3, 2025
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™ 2.0 RF Ablation System K233830 (S.E. 2/28/2024) – primary predicate The predicate devices have not been subject to a design related recall.

Description of Device	This 510(k) submission is for labeling changes to the OsteoCool™ 2.0 RF Ablation System cleared in K233830 (S.E. 2/28/2024). The primary change was removal of a warning for ablation of lesions due to multiple myeloma. The subject OsteoCool™ 2.0 RF Ablation Systems include the following hardware components: 1. OsteoCool™ 2.0 Radiofrequency (RF) Generator 2. OsteoCool™ 2.0 Peristaltic Pump & Pump Cable 3. OsteoCool™ 2.0 Connector Hub 4. OsteoCool™ Cart The OsteoCool™ 2.0 RF Ablation System includes the following commercially available sterile disposables that remain unchanged from the those cleared in K182497 (S.E. 12/17/2018): 5. OsteoCool™ RF Ablation Probe with Tube Kit 6. OsteoCool™ Independent Thermocouple with Introducer Kit: 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 RF Generator operates together with the RF Ablation Probe to deliver the RF energy to the target ablation site(s). The Tube Kit is used with the Peristaltic Pump to circulate water internally through the RF Ablation Probe(s) during RF energy delivery. The Pump Cable connects the Peristaltic Pump to the RF Generator, which controls the pump's flow. The Connector Hub connects the RF Ablation Probe(s) and Thermocouple(s) to the RF Generator. The Thermocouple Monitor is used with the 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 devices is substantially equivalent to the predicate devices.
	The subject and predicate devices are identical in fundamental scientific technology, principles of operation and mechanism of action, and design and technological aspects.

	OsteoCool™ 2.0 RF Ablation System **SUBJECT DEVICE**	***OsteoCool™ 2.0 RF Ablation System*** **PREDICATE DEVICE**	
510(k) Clearance	TBD	K233830 (S.E. 2/28/2024)	
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	Identical
Product Code	GEI	GEI	Identical
Product Class	Class II	Class II	Identical
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™ 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.	Identical
User	Physicians trained in the use of OsteoCool RF ablation system	Physicians trained in the use of OsteoCool RF ablation system	Identical
Anatomical Site of Use	Bone	Bone	Identical
Method of Access	Percutaneous	Percutaneous	Identical

TECHNICAL DETAILS - System			
FEATURE	***OsteoCool™ 2.0 RF Ablation System*** **SUBJECT DEVICE**	***OsteoCool 2.0 RF Ablation System*** **PREDICATE DEVICE**	
Energy Type	Radiofrequency	Radiofrequency	Identical
Principle of Operation	Radiofrequency energy delivered by operator from generator	Radiofrequency energy delivered by operator from generator	Identical
Mechanism of Action	Thermal coagulation necrosis	Thermal coagulation necrosis	Identical
Energy Delivery Control Mechanism	Temperature controlled	Temperature controlled	Identical
Probe Active Tip Size	7mm, 10mm, 15mm, 20mm	7mm, 10mm, 15mm, 20mm	Identical
Probe Outer Diameter	17Gauge	17Gauge	Identical
Probe length	16 cm	16 cm	Identical
Probe Electrodes Material	Stainless Steel	Stainless Steel	Identical
Probe Dielectric Materials	Polyimide	Polyimide	Identical
Electrode Sterilization	EtO, single use	EtO, single use	Identical
Compatible RF Generator	OsteoCool 2.0	OsteoCool 2.0	Identical
Number of independent thermocouples	4	4	Identical
Number of probes	4	4	Identical

TECHNICAL DETAILS - System			
FEATURE	***OsteoCool™ 2.0 RF Ablation System*** **SUBJECT DEVICE**	***OsteoCool 2.0 RF Ablation System*** **PREDICATE DEVICE**	
Generator Power Output Channels	4	4	Identical
Generator Maximum Output Power	• 80 Watts total • 20 W/channel	• 80 Watts total • 20 W/channel	Identical
Generator Maximum Voltage	224 V_{RMS}	224 V_{RMS}	Identical
Generator Maximum Current	1.2 A_{RMS}	1.2 A_{RMS}	Identical
Generator Output Frequency	465.1 KHz	465.1 KHz	Identical

TECHNICAL DETAILS - System			
FEATURE	***OsteoCool™ 2.0 RF Ablation System*** **SUBJECT DEVICE**	***OsteoCool 2.0 RF Ablation System*** **PREDICATE DEVICE**	
Default Ablation Temperature	70C (Gradual)	70C (Gradual)	Identical
	75C (Accelerated)	75c (Accelerated)	Identical
Electrode cooling flowrate	40 mL/min (Gradual)	40 mL/min (Gradual)	Identical
	30 mL/min (Accelerated)	30 mL/min (Accelerated)	Identical
Cooling medium	Sterile water	Sterile water	Identical

TECHNICAL DETAILS - System			
FEATURE	***OsteoCool™ 2.0 RF Ablation System*** **SUBJECT DEVICE**	***OsteoCool 2.0 RF Ablation System*** **PREDICATE DEVICE**	
System components	Pump OC02-100 Hub OC04-100	Pump OC02-100 Hub OC04-100	Identical
	Single Probe Kit 7 mm -OCP107 Single Probe Kit 10 mm -OCP110 Single Probe Kit 15 mm -OCP115 Single Probe Kit 20 mm -OCP120 Dual Probe Kit 7 mm x2 -OCP207 Dual Probe Kit 10 mm x2 -OCP210 Dual Probe Kit 15 mm x2 -OCP215 Dual Probe Kit 20 mm x2 -OCP220 RF Pump - OC02 ITC 28G - OCN001	Single Probe Kit 7 mm -OCP107 Single Probe Kit 10 mm -OCP110 Single Probe Kit 15 mm - OCP115 Single Probe Kit 20 mm -OCP120 Dual Probe Kit 7 mm x2 -OCP207 Dual Probe Kit 10 mm x2 -OCP210 Dual Probe Kit 15 mm x2 -OCP215 Dual Probe Kit 20 mm x2 -OCP220 RF Pump - OC02 ITC 28G - OCN001	Identical

Performance Data	To support the labeling changes, a systematic literature review was conducted to evaluate the safety of RFA for patients with multiple myeloma to ensure labeling is aligned with current practice. In addition to the literature review, a retrospective chart review and meta-analysis were conducted to assess all available clinical evidence for the performance and safety of RFA, and specifically the OsteoCool bone tumor ablation system, for the treatment of bone lesions associated with multiple myeloma.
Conclusion	The subject and predicate device are identical in fundamental scientific technology, including principles of operation and mechanism of action. Differences in the labeling between the subject and predicate devices do not raise any new concerns of safety and effectiveness. Therefore, Medtronic believes the subject devices are substantially equivalent to the predicate OsteoCool™ 2.0 RF Ablation System cleared in K233830 (S.E. 2/28/2024).