October 1, 2019

Medtronic, Inc.
Choua Thao
Senior Regulatory Affairs Specialist
3800 Annapolis Lane
Plymouth, Minnesota 55447

Re: K191526
Trade/Device Name: Cardioblate CryoFlex Surgical Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: July 2, 2019
Received: July 5, 2019

Dear Choua Thao:

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/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 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 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 Fellman
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191526

Device Name
Cardioblate CryoFlex Surgical Ablation System

Indications for Use *(Describe)*

For models 60SF2, 60SF3, and 60SF7:
The Cardioblate CryoFlex surgical ablation system is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The Cardioblate CryoFlex 7 cm, 10 cm, and 10-S probes and the Surgical Ablation Console freeze target tissue and block the electrical conduction pathways by creating an inflammatory response and cryonecrosis.

For model 60CM1:
The Cardioblate CryoFlex Surgical Ablation System is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The Cardioblate CryoFlex Clamp and Surgical Ablation Probe and the Surgical Ablation Console freeze target tissue and block the electrical conduction pathways by creating an inflammatory response and cryonecrosis.

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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5.0 510(k) Summary of Safety and Effectiveness

Date Prepared: June 7, 2019

Submitter:
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Establishment Registration Number: 3008592544

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Device Name and Classification

Trade Name:	Cardioblate™ CryoFlex™ Surgical Ablation System
Common Name:	Cryosurgical System
Product Code:	OCL
Regulation Number:	21 CFR 878.4400
Product Classification:	Class II
Classification Name:	Surgical Device, for Ablation of Cardiac Tissue

Predicate Device

K123733	Cardioblate™ CryoFlex™ Surgical Ablation System

Device Description

System and Accessories

The Medtronic Cardioblate™ CryoFlex™ Console, Cardioblate™ CryoFlex™ surgical ablation probes, and accessories are used together as a system. The system is comprised of the following components:

Table 5-1: Cardioblate™ CryoFlex™ Surgical Ablation Probes, Console, and Accessories

510(k) Number & Clearance Date	Model Number	Device Description
K123733 Clearance Date: 01-Apr-2013	65CS1	Cardioblate™ CryoFlex™ Surgical Ablation Console
	R65CS1	Cardioblate™ CryoFlex™ Surgical Ablation Console, Refurbished
	60SF2	Cardioblate™ CryoFlex™ Surgical Ablation Probe, 10 cm
	60SF3	Cardioblate™ CryoFlex™ Surgical Ablation Probe, 10-S cm
	60SF7	Cardioblate™ CryoFlex™ Surgical Ablation Probe, 7 cm
	60CM1	Cardioblate™ CryoFlex™ Surgical Ablation Probe with Clamp, 10 cm
	67RAXNA	Tank Regulator
	R67RAXNA	Tank Regulator, Refurbished
	65TC1	Tank Carrier
	67H08	Gas Hose
	671PCNA	Power Cord, North America
	67PS6	Pressure Transducer Cable, 6ft

System Overview

The Medtronic Cardioblate™ CryoFlex™ Surgical Ablation System is an argon based cryosurgical system intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The Cardioblate™ CryoFlex™ 7 cm, 10 cm, and 10-S probes, the Cardioblate™ CryoFlex™ clamp, and the Cardioblate™ CryoFlex™ Ablation Console freeze target tissue and block the electrical conduction pathways by creating an inflammatory response and cryonecrosis. The system utilizes an argon-based cryogen for fast, controlled freezing.

Cardioblate™ CryoFlex™ Surgical Ablation Probes

The Cardioblate™ CryoFlex™ clamp and surgical ablation probes are single use, disposable cryoablation probes that are designed for use with the Cardioblate™ CryoFlex™ surgical ablation system. The probes include integrated thermocouple for monitoring temperature at the ablation segment. The clamp and surgical ablation probes are supplied sterile and cannot be reused or re-sterilized.

The probe's shaft and ablation segment are made of specially heat-treated stainless steel. The shaft is designed with enough malleability that the surgeon can shape it, while still maintaining enough stiffness to ensure its stability in the operating field.

The malleable ablation segment has a bellows configuration, which provides kink resistance and thermal performance. A moveable insulative sleeve on the shaft allows the surgeon to vary the size of the ablation zone.

The probe has a 3-m (10 ft) connection hose which is to be handed out of the sterile field to an operating room nurse for connection to the control panel.

Indications for Use

60SF2, 60SF3, 60SF7:	The Cardioblate CryoFlex surgical ablation system is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The Cardioblate CryoFlex 7 cm, 10 cm, and 10-S probes and the Surgical Ablation Console freeze target tissue and block the electrical conduction pathways by creating an inflammatory response and cryonecrosis.
60CM1:	The Cardioblate CryoFlex Surgical Ablation System is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The Cardioblate CryoFlex Clamp and Surgical Ablation Probe and the Surgical Ablation Console freeze target tissue and block the electrical conduction pathways by creating an inflammatory response and cryonecrosis

Contraindications

The Cardioblate™ CryoFlex™ surgical ablation probe is not designed for use inside a beating heart.

Comparison to Predicate Devices

The Medtronic Cardioblate™ CryoFlex™ Surgical Ablation System is substantially equivalent to the predicate surgical ablation system (K123733). A comparison of the proposed modified devices to the currently marketed predicate devices indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same shelf life
- Same operating principle
- Substantially equivalent material
  - The connector of the Cardioblate™ CryoFlex™ Surgical Ablation Probe is changing; therefore, new components are necessary for the updated design
- Substantially equivalent design features
  - The internal design feature of the probe is not changing (the electrical contacts are still in physical contact with the console); only the external design is changing, the new design allows for easier one-handed attachment and removal of the probe to the console connector

Table 5-2: Device Characteristics and Features Summary

Device Characteristics and Features	Predicate *(K123733)*	This Submission *(K191526)*	Substantial Equivalence
	Cardioblate™ CryoFlex™ Disposable Probes	**Cardioblate™ CryoFlex™ Disposable Probes**	
Therapy Delivery			
Facilitates pneumatic connection to the console	✓	✓	Yes
Secures the electrical connection of the probe's thermocouple to the console	✓	✓	Yes
Argon gas is transferred from the console through the pneumatic stem in the connector and into the probe to provide a cooling effect	✓	✓	Yes
User Interface			
Same console connection port	✓	✓	Yes
Connection to console	✓	✓	Yes
Pneumatic stem that locks into a female quick disconnect fitting on the console	✓	✓	Yes
Connectors are pushed onto the console to form the connection and a pin must be removed prior to use	✓	✓	Yes
External Pull Pin	✓	✓	Yes
Connector is removed by achieving both hands by depressing the "clips" with one hand and retracting the console's female quick disconnect fitting with the other hand	✓	---	Yes
Connector is removed by using a single hand by depressing a button that automatically rises during connection	---	✓	Yes
Connector			Yes

Conclusion

In conclusion, the information included in this submission demonstrates that the Cardioblate™ CryoFlex™ surgical ablation probe, with the updated connector to facilitate gas connection and disconnection to the console is substantially equivalent to the legally marketed predicate devices.