December 22, 2022

Medtronic Inc.
Rajitha Nair
Sr. Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55448

Re: K223508
Trade/Device Name: Cardioblate Gemini-s 49260 Surgical Ablation Device; Cardioblate Gemini-s 49351 Surgical Ablation Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: November 21, 2022
Received: November 22, 2022

Dear Rajitha Nair:

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223508

Device Name
Cardioblate Gemini-s 49260 Surgical Ablation Device; Cardioblate Gemini-s 49351 Surgical Ablation Device

Indications for Use *(Describe)*
The Cardioblate™ Gemini™ Surgical Ablation Device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy. The system is indicated for use, under direct or endoscopic visualization, in surgical procedures, including minimally invasive surgical procedures.

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.

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510(k) Summary

Submitter

Date Prepared: November 21, 2022

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
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Establishment Registration Number: 2184009

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Device

Trade Name	Common Name	Classification Name	Classification	Classification Panel	Regulation	Product Code
Cardioblate Gemini-s 49260 Surgical Ablation Device	Electrosurgical device	Electrosurgical cutting and coagulation device and accessories	Class II	Cardiovascular	21 CFR 878.4400	OCL
Cardioblate Gemini-s 49351 Surgical Ablation Device						

Predicate Device

Trade Name	510(k)	Clearance Date
Cardioblate Gemini-s 49260 Surgical Ablation Device	K121767	7/13/2012
Cardioblate Gemini-s 49351 Surgical Ablation Device	K200514	6/3/2020

No reference devices were used in this submission.

Device Description

The Cardioblate Gemini surgical ablation device (Model 49260, Model 49351), figure 1 below, is a hand-held, single-use, bipolar, radio-frequency (RF) ablation device for use in cardiac surgery. It has a saline irrigation system to deliver fluid at the contact point between the tissue and electrode to cool the tissue during RF energy delivery. This device is intended for intermittent operation

Model 49260 of the Cardioblate Gemini surgical ablation device is intended for use with Cardioblate 68000 Generator (figure 2), whereas Model 49351 is intended for use with the Valleylab™ FT10 Energy(figure 3), whereas model 49260 is intended for use with Cardioblate 68000 Generator(figure 3). The devices are provided sterile and nonpyrogenic, are disposable, and are for single use only. They are sterilized using ethylene oxide.

The Cardioblate Gemini-s is a bipolar electrode device that transmits radio frequency energy, generated by an external generator, between the two electrodes. The device has dual linear electrodes, 6.3 cm in length, with integral fluid delivery to the electrodes. The Gemini-s device is port accessible, intended for open or closed chest procedures to ablate tissue through resistive heating due to radiofrequency energy passing through tissue. The device is designed to reproduce the Cox-Maze lesion pattern by creating linear transmural lesions in both atria of the heart during cardiac procedures.

The Gemini-s surgical ablation device has a flexible neck design that provides the physician with the ability to access various anatomies utilizing a neck curve through the full range from 0 to 180-degree configuration.

Once the electrodes are correctly positioned, the parallel jaws lock by squeezing the handle. The electrodes have full contact with the tissue and the locking mechanism must be fully engaged to ensure accurate transmurality readings. Simultaneous with the actuation of the trigger and jaw closure is the opening of the (normally closed) fluid path to start the flow of saline. The device automatically shuts off the saline when the jaws are open and when the device is not in use.

Figure 1: Cardioblate Gemini-s (Model 49260, 49351)

Figure 2 Cardioblate 68000 Generator Medtronic VLFT10GEN Generator

Figure 3: Medtronic VLFT10GEN Generator

Principles of Operation

The device applies endocardial or epicardial radiofrequency energy. The energy platform monitors tissue impedance and adjusts the amount of power delivered to the tissue between the active electrodes to create transmural lesions in the intracardiac tissue. Irrigated Radiofrequency Frequency (RF) ablation uses medium frequency alternating current to generate heat, which destroys abnormal electrical conduction pathways while cooling the cardiac tissue. Radiofrequency (RF) ablation is a procedure where medium frequency (434 KHz ± 10%) energy is delivered into cardiac tissue. The radiofrequency energy is delivered from a generator, through the irrigated electrode (patient contacting end of hand-held device) and into the tissue. When the energy encounters the higher impedance of cardiac tissue, heat is produced, causing cells to die. As tissue temperature rises above 113° F (50° C), protein is permanently damaged and cell membranes fuse causing irreversible cardiac cell death. Once the cells are no longer viable, they are unable to propagate electrical signals. This type of electrical energy has been used in medical procedures for decades.

Indications for Use

The Cardioblate® Gemini® Surgical Ablation Device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy. The system is indicated for use, under direct or endoscopic visualization, in surgical procedures, including minimally invasive surgical procedures.

Comparison of Technological Characteristics with the Predicate Device

When compared to the predicate devices, the Cardioblate Gemini Surgical Ablation Devices presented in this submission have the same:

- intended use/indications for use
- contraindications
- operating principle
- energy type

- mechanism of action
- radiofrequency generator and delivery system
- patient contacting materials
- shelf life
- sterilization process
- dimensions
- performance
- irrigation
- Electrical
- packaging configuration and materials

When compared to the predicate devices, the Cardioblate Gemini Surgical Ablation Devices presented in this submission have the following differences:

- IFU updates (new warning and updated directions for use)

Performance Data

The modifications described in this Special 510(k) Notification were verified through design verification testing. The Design Failure Modes and Effects Analysis (DFMECA) file was updated along with the Risk Management File to reflect the current status and risk evaluations at the device and system level. Risk Assessment concluded that no new biocompatibility testing was needed for the proposed Cardioblate Gemini Surgical Ablation Devices because there are no changes to:

- Intended use
- Technological characteristics
- Operating principle
- Design features
- Device and packaging materials
- Sterilization requirements
- Shelf life

Conclusions

The Predicate devices are legally marketed under K121767 (49260) and K200514 (49351), have the same intended use, and the same technological and performance characteristics as the subject devices. The proposed change to the IFU adds a new warning to align with the DFMECA. Additionally, directions for use have been updated to provide additional clarity and minimize use error. These changes do not arise from different technological characteristics of the devices or raise different questions of safety and effectiveness.

In summary, this submission demonstrates that the Cardioblate Gemini Ablation Devices are substantially equivalent[1] to the legally marketed predicate devices.

[1] The term 'substantially equivalent' as used herein is intended to be a determination of substantial equivalency under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters." (Federal Register, Vol. 42, No. 163, Aug. 23, 1977, page 42525 and 42529).