June, 3, 2020

Medtronic
Rahul Shah
Principal Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K200514
Trade/Device Name: Cardioblate Gemini-s Surgical Ablation Device, Model 49351
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OCL
Dated: April 8, 2020
Received: April 10, 2020

Dear Rahul Shah:

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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200514

Device Name
Cardioblate Gemini-s Surgical Ablation Device, Model 49351

Indications for Use *(Describe)*
The Cardioblate Gemini-s surgical ablation device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: February 28, 2020

Submitter: Medtronic, Inc.
Medtronic Perfusion Systems
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Establishment Registration Number: 2184009

Contact Person: Rahul Shah
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Device Name and Classification

Trade Name:	Cardioblate Gemini-s Surgical Ablation Device, Model 49351
Common Name:	Electrosurgical device
Classification name	Electrosurgical cutting and coagulation device and accessories
Classification:	Class II
Regulation Number:	21 CFR 878.4400
Product Code:	OCL

Name of Predicate Device

K121767 Cardioblate Gemini-s Surgical Ablation Device, Model 49260

Name of Reference Device

K191601 Valleylab™ FT10 Energy Platform, Model VLFT10GEN

Device Description

The Cardioblate Gemini-s surgical ablation device (Model 49351) 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.

The proposed Cardioblate Gemini-s device is intended for use with the Valleylab™ FT10 Energy Platform (VLFT10GEN) with software version 3.0.0 or higher.

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.

Indications for Use

The Cardioblate Gemini-s surgical ablation device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy. The system is indicated for use, under direct or endoscopic visualization, in surgical procedures, including minimally invasive surgical procedures.

Contraindications

The Cardioblate Gemini-s surgical ablation device should not be used for:

- Patients that have active endocarditis at time of surgery
- Ablation in a pool of blood (for example, through a purse string suture on a beating heart) (Effects of this type of ablation are unknown.)

Comparison to Predicate Devices

When compared to predicate devices (K121767), the Cardioblate Gemini-s Surgical Ablation Device presented in this submission have the same:

- Intended Use and Contraindications
- Technological characteristics and operating principle
- Design features
- Performance specifications
- Patient contacting components and materials
- Shelf life
- Packaging design and configuration

When compared to predicate devices (K121767), the Cardioblate Gemini-s Surgical Ablation Device presented in this submission have the following key differences:

- New plug connector for VLFT10GEN compatibility
- IFU, Label and shelf carton branding updates
- Branding – Medtronic logo print on the handle of Gemini-s

Accessories:

The Cardioblate Gemini-s requires two connections: a fluid connection to the saline source, and an electrical connection to the radio frequency generator (reference device, VLFT10GEN).

The saline source connection is a standard luer connection designed for a commercially available standard saline bag pressurized using a pressure cuff. The electrical connection enables ablation that can be activated/deactivated with the use of a hand switch.

Performance Testing

Performance testing was completed to demonstrate substantial equivalence of the system (the proposed Cardioblate Gemini-s surgical ablation devices, when used with the Valleylab FT10 Energy Platform, software version 3.0 or higher) to the identified predicate. Clinical and non-clinical animal testing was not required to establish substantial equivalence. The subject device underwent the following verification and validation testing, as applicable:

Mechanical: Mechanical verification testing was conducted for components of the subject devices to ensure compliance with current IEC 60601-1 and IEC 60601-2-2 standard requirements and Medtronic self-enforced requirements.

Electrical: Electrical verification testing was conducted for the subject devices to ensure compliance with current IEC 60601-1 and IEC 60601-2-2 electrical requirements.

Electromagnetic compatibility: Electromagnetic compatibility testing was completed for the subject devices to ensure compliance with current IEC 60601-1-2 standard requirements.

Benchtop Lesion Verification: Comparative lesion verification testing was performedusing a soft tissue model to demonstrate the substantially equivalent ablation performance of the subject and predicate systems.

Usability: Testing was performed to verify and validate the usability requirements of the subject devices as a system. Elements captured included normal use cases, a foreseeable worst-case use scenario, and testable requirements for primary operating functions.

Conclusion

Verification and validation test results demonstrate that the subject devices are substantially equivalent to the predicates cleared in K121767. Differences between the subject and predicate devices do not raise different questions of safety and effectiveness. The intended use of the devices has not changed. Moreover, the fundamental scientific technology, operating principle, and design features are unchanged from that of the predicate.