May 30, 2019

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

Re: K190623
Trade/Device Name: Cardioblate 49313 Surgical Ablation Pen,
Cardioblate 49314 Surgical Ablation Pen
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OCL
Dated: April 2, 2019
Received: April 3, 2019

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,

Bram D. Zuckerman, M.D.
Director
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)*
K190623

Device Name
Cardioblate 49313 Surgical Ablation Pen
Cardioblate 49314 XL Surgical Ablation Pen

Indications for Use *(Describe)*

Cardioblate 49313 Surgical Ablation Pen
The Cardioblate surgical ablation pen is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Cardioblate 49314 XL Surgical Ablation Pen
The Cardioblate XL surgical ablation pen is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

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: March 8, 2019

Submitter: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establishment Registration Number: 2184009

Contact Person: Rahul Shah
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Device Name and Classification

Trade Name:	Cardioblate 49313 Surgical Ablation Pen
	Cardioblate 49314 XL Surgical Ablation Pen
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

K080509 Cardioblate Monopolar Pens, Models 60813 and 60814

Name of Reference Device

K182610 Valleylab™ FT10 Energy Platform, Model VLFT10GEN

Device Description

The Cardioblate Surgical Ablation devices (Pen and XL Pen, Model 49313 and 49314 respectively) are hand held, single use, monopolar, RF ablation devices for use in cardiac surgery. Each device has a saline irrigation system to deliver fluid at the contact point between the tissue and electrode tip to cool the tissue during RF energy delivery. The devices are intended for intermittent operation.

The proposed Cardioblate Pen and XL Pen devices are intended for use with the Valleylab™ FT10 Energy Platform (VLFT10GEN) with software version 3.0.0 or higher.

These devices are sterile, nonpyrogenic, disposable, and single use only. They are sterilized using ethylene oxide

Indications for Use

Cardioblate Pen (49313)

The Cardioblate surgical ablation pen is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Cardioblate XL Pen (49314)

The Cardioblate XL surgical ablation pen is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Comparison to Predicate Devices

When compared to predicate devices (K080509), the Cardioblate Surgical Ablation Devices (Pen and XL Pen) 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

When compared to predicate devices (K080509), the Cardioblate Surgical Ablation Devices (Pen and XL Pen) presented in this submission have the following differences:

- Cardioblate Monopolar (Pen and XL Pen) Devices
  - New plug connector for VLFT10GEN compatibility
  - IFU and Labeling updates
  - eIFU rather than paper IFU
- Cardioblate Monopolar (standard) Pen only
  - Packaging

Performance Testing

Performance testing was completed to demonstrate substantial equivalence of the system (the proposed Cardioblate surgical ablation devices (Pen and XL Pen), used with the Valleylab FT10 Energy Platform, software version 3.0 or higher) to the identified predicate system. Clinical and non-clinical animal testing was not required to establish substantial equivalence. The system components were subjected to 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 performed using 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.

Packaging: Packaging sterile barrier system performance testing was conducted for the proposed devices in their final packaging in accordance with ISO 11607-1.

Conclusion

Verification and validation test results demonstrate that the proposed devices are substantially equivalent[1] to the predicates cleared in K080509. Differences between the proposed 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.

[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).