December 19, 2018

Medtronic
Kari Christianson
Principal Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K182610
Trade/Device Name: Valleylab FT10 Electrosurgical Platform, Cardioblate BP2 Surgical Ablation Device, Cardioblate LP 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, GEI
Dated: November 12, 2018
Received: November 13, 2018

Dear Kari Christianson:

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.

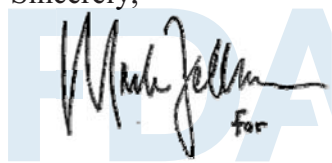
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Division of Cardiovascular Devices
Office of Device Evaluation
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)*

K182610

Device Name
Valleylab FT10 Energy Platform
Cardioblate BP2 49321 Surgical Ablation Device
Cardioblate LP 49341 Surgical Ablation Device

Indications for Use *(Describe)*

Valleylab FT10 Energy Platform:
The Valleylab FT10 Energy Platform is a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue. When used with compatible sealing devices, it is indicated for sealing vessels up to and including 7 mm, tissue bundles, and lymphatics. When used with compatible ablation devices, it is indicated for cardiac tissue ablation. The generator can also be used with compatible resectoscopes for endoscopically controlled removal or coagulation of tissue using 0.9% NaCl solution as the irrigation medium.

The tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

Cardioblate BP2 49321 Surgical Ablation Device:
The Cardioblate® BP2 surgical ablation device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Cardioblate LP 49341 Surgical Ablation Device:
The Cardioblate® LP surgical ablation device 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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K182610

Medtronic

510(k) Summary

Date Prepared: September 19, 2018

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

Contact Person: Kari Christianson
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Common Name: Electrosurgical device

Classification Name: Electrosurgical cutting and coagulation device and accessories

Trade Name: Cardioblate Surgical Ablation System

Classification: Class II

Panel: Cardiovascular

Regulation: 21 CFR 878.4400

Product Code: OCL

Predicate Devices: Cardioblate 68000 Generator (68000)
K080509, cleared 05/05/2008

Valleylab FT10 Energy Platform (VLFT10GEN),
K080509, cleared 05/05/2008
K181389, cleared 06/19/2018

Cardioblate Surgical Ablation System (60831, 60841),
K080509 K093203, cleared 02/26/2010

Device Description

Valleylab FT10 Energy Platform (VLFT10GEN)

The Valleylab™ FT10 Energy Platform (VLFT10GEN) is a multifunction generator which provides radio frequency (RF) energy for monopolar and bipolar surgical applications, tissue-fusion and vessel-sealing applications (LigaSure/vessel-sealing function), and cardiac tissue ablation. The Cardioblate™ instruments that allow the cardiac ablation capability (49321, 49341) are single use. The Cardioblate ablation energy delivery is only available when using compatible instruments.

The VLFT10GEN is used in hospitals and other health care facilities where surgical procedures are carried out.

The VLFT10GEN can be used with a variety of legally marketed accessories including monopolar and bipolar instruments, footswitches, and return electrode pads. The VLFT10GEN connects to electrical mains and operates at an input line frequency of 47-63 Hz.

Cardioblate BP2 (49321) and LP (49341) Surgical Ablation Devices:

The Cardioblate BP2 and LP Surgical Ablation Devices are hand held, single use, bipolar, RF ablation device for use in cardiac surgery. They have a saline irrigation system to deliver fluid at the contact point between the tissue and electrode to cool the tissue during RF energy delivery. The devices are intended for intermittent operation. The Cardioblate BP2 and LP devices are dual linear electrode devices that have integral fluid delivery to both electrodes. They rapidly create linear transmural lesions in both atria of the heart during cardiac surgical procedures.

Description of Changes

The following design changes are being made to the devices:

- VLFT10GEN
    - Addition of a Cardioblate software module
    - Addition of cardiac tissue ablation to Indications for Use
    - IFU and Labeling updates
- Cardioblate BP2 and LP Devices
    - New connectors for VLFT10GEN compatibility
    - RFID, rather than EPROM, device tracking
    - IFU and Labeling updates
    - Branding change
    - eIFU rather than paper IFU

Indications for Use

Valleylab FT10 Energy Platform (VLFT10GEN):

The Valleylab FT10 Energy Platform is a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue. When used with compatible sealing devices, it is indicated for sealing vessels up to and including 7 mm, tissue bundles, and lymphatics. When used with compatible ablation devices, it is indicated for cardiac tissue ablation. The generator can also be used with compatible resectoscopes for endoscopically controlled removal or coagulation of tissue using 0.9% NaCl solution as the irrigation medium. The tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

Cardioblate BP2 (49321):

The Cardioblate BP2 surgical ablation device is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Cardioblate LP (49341):

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

Contraindications

Valleylab FT10 Energy Platform (VLFT10GEN):

The cardiac tissue ablation feature is contraindicated for patients that have active endocarditis at the time of surgery. Ablation in a pool of blood is contraindicated (for example, through a purse string suture).

Cardioblate BP2 (49321):

The Cardioblate BP2 surgical ablation device should not be used for:

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

Cardioblate LP (49341):

The Cardioblate LP Surgical Ablation devices 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 (K080509, K181389, K923203), the Valleylab FT10GEN Energy Platform used with Cardioblate BP2 and LP surgical ablation devices presented in this submission have the same:

- Same Intended Use (Models 49321 and 49341)
- Same technological characteristics and operating principle
- Same design features
- Same performance specifications
- Same patient contacting components and materials (Models 49321 and 49341)
- Same shelf life (Models 49321 and 49341)

Performance Testing

Performance testing was completed to demonstrate substantial equivalence of the system (the proposed Cardioblate BP2 and LP surgical ablation devices, used with the Valleylab FT10GEN 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.

Software: Software verification and validation was completed. FDA's current "Guidance for the content of premarket submissions for software contained in Medical Devices" was used to determine the Level of Concern for the software in the subject devices.

All test requirements were met as specified by applicable standards and the test protocols.

Conclusion

The fundamental scientific technology of the Cardioblate BP2 and LP surgical ablation devices when used with the Valleylab FT10GEN Energy Platform, including principles of operation and mechanism of action, is the same as the predicate devices. Differences in design and technological characteristics between the proposed and predicate devices do not raise any new

types of questions of safety and effectiveness. Verification and validation test results support the substantial equivalence of the system, as compared to the predicate system.

The data included in this submission is sufficient to provide reasonable assurance of the safety and effectiveness of the subject devices with proposed design changes and they are substantially equivalent to the marketed predicate devices.