July 12, 2019

Covidien
Ms. Jennie van Diemen
Regulatory Affairs Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Re: K191601
Trade/Device Name: Valleylab FT10 Energy Platform
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 13, 2019
Received: June 17, 2019

Dear Ms. Jennie van Diemen:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K191601

Device Name
Valleylab FT10 Energy Platfom

Indications for Use *(Describe)*
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.

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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COVIDIEN

510(k) Summary

Date summary prepared: July 5, 2019

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact:
Ms. Jennie van Diemen
Regulatory Affairs Specialist
Telephone: 303-581-7037
Fax: 303-530-6313
Email: jennie.vandiemen@medtronic.com

Name of Device

Trade Name:	Valleylab FT10 Energy Platform
Catalog Numbers:	VLFT10GEN
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI, OCL)

Predicate Device

Trade Name:	Valleylab FT10 Energy Platform
Catalog Number:	VLFT10GEN
Common Name:	Electrosurgical Generator
510(k) Number:	K182610 (cleared 12/19/2018)
Manufacturer:	Covidien
Recalls:	This device has not been subject to a design-related recall

Reference Device

Trade Name:	Valleylab FX8 Energy Platform
Catalog Number:	VLFX8GEN
Common Name:	Electrosurgical Generator
510(k) Number:	K181389 (cleared 06/25/2018)
Manufacturer:	Covidien
Recalls:	This device has not been subject to a design-related recall

Device Description
The Valleylab™ FT10 Energy Platform (VLFT10GEN) provides radio frequency (RF) energy for monopolar and bipolar surgical applications, tissue-fusion and vessel-sealing applications (LigaSure vessel-sealing function), and cardiac ablation. It is a combination of a full-featured general-surgery electrosurgical unit, a bipolar vessel sealing system, and an ablation unit. The monopolar and bipolar sections, including the LigaSure section of the system, are isolated outputs that provide the appropriate power for cutting, desiccating, and fulgurating tissue during monopolar and bipolar surgery. The LigaSure vessel-sealing section of the system provides power for vessel sealing. The cardiac ablation feature of the device is only available when used with compatible Cardioblate™ 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.

Indications for Use
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.

Contraindications
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).

Comparison of Technological Characteristics with the Predicate Device
The Valleylab FT10 Energy Platform with the proposed software modifications has similar technological and performance characteristics as the predicate Valleylab FT10 Energy Platform cleared in K182610. Both versions of the energy platform are a combination of a full-featured general-surgery electrosurgical system, a vessel sealing system, and a cardiac ablation system. The Valleylab FX8 Energy Platform, cleared by K181389, serves as a reference device and test control device for the adoption of bipolar modes by the proposed device. The proposed Valleylab FT10 Energy Platform provides incremental improvements over the predicate while maintaining the same basic functionality and intended use. These improvements are summarized below.

- Addition of bipolar modes Precise, Standard, and Macro
- Improved Bipolar Resection Cut mode initiation speed
- Feature allowing the user to save settings and access recent settings
- Bug fixes associated with non-safety related issues

Performance Characteristics
Verification and validation testing confirmed that the modifications to the Valleylab FT10 Energy Platform do not raise different questions of safety and effectiveness. The testing confirmed the continued conformance to applicable technical design specifications and performance requirements, including requirements associated with industry safety and performance standards, as follows:

- *Ex vivo* testing using porcine tissue showed comparable performance with regards to thermal spread
- System verification showed the VLFT10GEN possesses all required functionality and meets system specifications
- Software verification and validation testing was conducted in accordance with FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* [2005]and IEC 62304 *Medical device software – Software life cycle processes*
- Confirmatory electrical safety testing showed the VLFT10GEN complies with the 2017 version of IEC 60601-2-2 *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories - Edition 6.0*
- Validation testing was conducted in accordance with FDA Guidance *Applying Human Factors and Usability Engineering to Medical Devices* [2016] and IEC 62366-1:2015 *Medical Devices – Application of Usability Engineering to Medical Devices*

Clinical Studies
This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusions
Verification and validation activities demonstrate that the Valleylab FT10 Energy Platform is substantially equivalent to the predicate Valleylab FT10 Energy Platform cleared in K182610. The intended use of the Valleylab FT10 Energy Platform has not changed. Moreover, the results of testing demonstrate that the software modifications do not affect the safety or performance of the energy platform.