DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 16, 2017

Covidien LLC
Ms. Sharon McDermott
Sr. Specialist, Regulatory Affairs
5920 Longbow Drive
Boulder, Colorado 80301

Re: K170170
Trade/Device Name: Valleylab FT10 Electrosurgical Platform
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 18, 2017
Received: January 19, 2017

Dear Ms. McDermott:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170170

Device Name
Valleylab FT10 Energy Platform

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. 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

COVIDIEN

510(k) Summary

Date summary prepared: 02/13/2017

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact

Sharon McDermott
Senior Specialist, Regulatory Affairs
Telephone: 303-581-6789
Fax: 303-530-6313
Email: sharon.l.mcdermott@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)

Predicate Device

Trade Name:	Valleylab FT10 Energy Platform
Catalog Number:	VLFT10GEN
Common Name:	Electrosurgical Generator
510(k) Number:	K151649 (cleared 10 Sept 2015)
Manufacturer:	Covidien
Recalls:	This device has not been subject to a design-related recall

Device Description

The Valleylab™ FT10 Energy Platform (VLFT10) provides radio frequency (RF) energy for monopolar and bipolar surgical applications, and tissue-fusion and vessel-sealing applications (LigaSure/vessel-sealing function). It is a combination of a full-featured general-surgery electrosurgical unit and a bipolar vessel sealing system. 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 VLFT10 is used in hospitals and other health care facilities where surgical procedures are carried out.

The VLFT10 can be used with a variety of legally marketed accessories including monopolar and bipolar instruments and a newly introduced bipolar adapter, footswitches, and return electrode pads. The VLFT10 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. 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.

Comparison of Technological Characteristics with the Predicate Device

The Valleylab FT10 with the proposed software modifications has the similar technological and performance characteristics as the predicate Valleylab FT10 cleared in K151649. Both versions of the energy platform are a combination of a full-featured general-surgery electrosurgical system and a vessel sealing system. The VLFT10 with software version 2.0 provides incremental improvements over the predicate while maintaining the same basic functionality and intended use. These are summarized below.

- Monopolar capabilities have been expanded with the addition of a Shared Coag mode, a mode that has been available in other electrosurgical generators such as Covidien's Force FX Electrosurgical Generator
- Enabling a second standard bipolar port via insertion of an adapter into the existing LigaSure/Bipolar port
- Updates to existing Auto-bipolar mode to improve user experience
- GUI changes to support second bipolar port and instruments under development

Performance Characteristics

The modifications made to the Valleylab FT10 Energy Platform were found to not affect safety or performance through design verification testing, which confirmed the continued conformance to applicable technical design specifications and performance requirements, including requirements associated with industry safety and performance standards, as follows:

- Basic safety and essential performance in accordance with IEC 60601-1:2005/A1:2012 and IEC 60601-2-2:2009
- Electromagnetic compatibility in accordance with IEC 60601-1-2:2014
- *Ex vivo* testing using porcine tissue showed comparable performance with regard to thermal effects
- System verification (Non-IEC electrical, instrument compatibility, basic functionality) showed that the VLFT10 has all required functionality and that it meets system specifications.
- Software verification and validation testing was conducted in accordance with FDA's, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*
- Usability testing in accordance with *IEC 62366: 2015Medical devices – Application of usability engineering to medical devices* showed that representative surgical tasks with the updated software.

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 the Valleylab FT10 with software version 2.0 is substantially equivalent to the predicate Valleylab FT10 Energy Platform cleared in K151649. The intended use of the Valleylab FT10 Energy Platform was not altered. Moreover, the results of testing demonstrate that the software modifications do not affect the safety or performance of the energy platform.