July 12, 2024

Covidien LLC
Aliva Mahunta
Sr. Regulatory Affairs Specialist
200 Medtronic Drive
Lafayette, Colorado 80026

Re: K241085
Trade/Device Name: Valleylab ™FT10 Energy Platform Software Version 5.0 (VLFT10GEN VLFT10FXGEN VLFT10LSGEN)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, OCL
Dated: May 23, 2024
Received: May 24, 2024

Dear Aliva Mahunta:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 H. Chen -S Digitally signed by Long H. Chen -S
Date: 2024.07.12 16:00:47 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241085

Device Name

Valleylab ™FT10 Energy Platform Software Version 5.0 (VLFT10GEN VLFT10FXGEN VLFT10LSGEN)

Indications for Use *(Describe)*

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 7mm thick tissue (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.

Valleylab ™FT10 Electrosurgical Generator (VLFT10FXGEN)

The VLFT10FXGEN is a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.

Valleylab ™FT10 Vessel Sealing Generator (VLFT10LSGEN)

The VLFT10LSGEN is a high frequency electrosurgical generator. When used with compatible sealing devices, it is indicated for sealing vessels up to and including 7 mm, tissue bundles, and lymphatics.

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.

510(k) Summary Complying with 21 CFR 807.92

I. **SUBMITTER**

Covidien llc.
200 Medtronic Drive
Lafayette, CO, 80026

Contact: Aliva Mahunta, Sr. Regulatory Affairs Specialist
Phone Number : 800-255-6774
Email: aliva.mahunta@medtronic.com
Date Summary Prepared: May 20, 2024

II. PROPOSED DEVICE

Trade Name:	Valleylab FT10 Energy Platform with Software Version 5.0
Catalog Numbers:	VLFT10GEN; VLFT10FXGEN; VLFT10LSGEN
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical cutting and coagulating device and accessories (21 CFR 878.4400)
Regulatory Class:	II
Product Code:	GEI, OCL

PREDICATE DEVICE

Trade Name:	Valleylab FT10 Energy Platform with Software Version 4.0
Catalog Numbers:	VLFT10GEN
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical cutting and coagulating device and accessories (21 CFR 878.4400)
510(k) Number:	K191601
Regulatory Class:	II
Product Code:	GEI, OCL

III. DEVICE DESCRIPTION

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. The generator provides radio frequency (RF) energy for monopolar and bipolar surgical applications, tissue-fusion, and vessel-sealing applications (LigaSure/vessel sealing function) and cardiac applications. 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/Bipolar section of the system, are isolated outputs that provide the appropriate power for cutting, desiccating, and fulgurating tissue during monopolar and bipolar surgery.

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.

Valleylab™ FT10 Electrosurgical Generator (VLFT10FXGEN): The Valleylab™ FT10 Electrosurgical Generator is a high frequency electrosurgical only version of the VLFT10GEN Energy Platform. It is intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.

Valleylab™ FT10 Vessel Sealing Generator (VLFT10LSGEN): The Valleylab™ FT10 Vessel Sealing Generator is the vessel sealing only version of the VLFT10GEN Energy Platform. It is a high frequency electrosurgical generator. When used with compatible sealing devices, it is indicated for sealing vessels up to and including 7 mm, tissue bundles, and lymphatics.

IV. 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 thick tissue (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.

Valleylab™ FT10 Electrosurgical Generator (VLFT10FXGEN):

The VLFT10FXGEN is a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.

Valleylab™ FT10 Vessel Sealing Generator (VLFT10LSGEN):

The VLFT10LSGEN is a high frequency electrosurgical generator. When used with compatible sealing devices, it is indicated for sealing vessels up to and including 7 mm, thick tissue (tissue bundles), and lymphatics.

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.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Valleylab FT10 Energy Platform with the proposed software modifications has the same technological and performance characteristics as the predicate Valleylab FT10 Energy Platform with software version 4.0 cleared in K191601. 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 proposed device VLFT10GEN with software version 5.0 (VLFT10GEN SW v5.0) provides

incremental improvements over the predicate while maintaining the same basic functionality and intended use.

Characteristic	Proposed Device Valleylab™ FT10 Energy Platform with Software version 5.0	Predicate Device Valleylab™ FT10 Energy Platform with Software version 4.0 (K191601)	Comparison
Classification Regulation	878.4400	878.4400	Same
Class	II	II	Same
Product Code	GEI	GEI	Same
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 thick tissue (tissue bundles), and lymphatics. When used with compatible ablation devices it is indicated for cardiac tissue ablation. The generator can 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. **VLFT10FXGEN Indications for Use** The VLFT10FXGEN Energy Platform is a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.	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	Same There is no change to the intended use or indications for use of the device. The indications for use for the separate VLFT10FXGEN and VLFT10LSGEN functions are simply a subset of the fully functional VLFT10GEN indications for use, which are not changing. The intended use was revised to add thick tissue (tissue bundles) while keeping tissue bundles. This revision is for clarification purposes only for the benefit of the surgeon. There is no change to the intended use of the generator, but rather a clarification of terms for the benefit of the surgeon.

	VLFT10LSGEN Indications for Use The VLFT10LSGEN Energy Platform is a high frequency electrosurgical generator. When used with compatible sealing devices, it is indicated for sealing vessels up to and including 7 mm tissue bundles, and lymphatics.		
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).	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).	Same
Physical Characteristics (approximate	Height: 7 in. (17.78 cm) Width: 14.5 in. (35.8 cm) Length: 18.2 in. (46.2 m) Weight: 22.3 lbs. (10.1 kg)	Height: 7 in. (17.78 cm) Width: 14.5 in. (35.8 cm) Length: 18.2 in. (46.2 m) Weight: 22.3 lbs. (10.1 kg)	Same
Touchscreen	LCD; Resistive Technology	LCD; Resistive Technology	Same
Connector Receptacles	LED Illuminated connector readers	LED Illuminated connector readers	Same
Monopolar Ports	2	2	Same
Bipolar/LigaSure Ports	2	2	Same
Hand switch Activation	Yes	Yes	Same
Footswitch Activation	Yes	Yes	Same
REM Quality Contact Monitoring	Yes	Yes	Same
Wireless Connectivity	No	No	Same
Instrument Identification	Barcode/RFID	Barcode/RFID	Same

VI. PERFORMANCE DATA

The following performance data were conducted in support of the substantial equivalence determination. Verification and Validation testing confirmed that the modifications to the Valleylab™ FT10 Energy Platform do not raise any different issues 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:

- System Verification showed that VLFT10GEN with SW v.5.0 possesses all required functionality and meets system specifications.
- Confirmatory Electrical safety and EMC testing were conducted on the Proposed Device and showed that the system complies with IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.
- Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Device Software Functions" [2023*] and IEC 62304 *Medical Device Software- Software life cycle processes*".
- Mechanical Testing in the form of Environmental and Packaging Test and Chemical Soak and Abrasion Test was conducted and met all the acceptance criteria.

VII. CLINICAL STUDIES

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

VIII. CONCLUSIONS

Verification and Validation activities demonstrate that the Valleylab™FT10 Energy Platform with software version 5.0 (VLFT10GEN SW v5.0) is substantially equivalent to the predicate Valleylab™FT10 Energy Platform with software version (VLFT10GEN SW v4.0) cleared in K191601. The intended use of the Valleylab™FT10 Energy Platform has not changed. The non-clinical data support the safety of the device and the hardware and software verification, and validation demonstrate that the Proposed Device Valleylab™FT10 Energy Platform with software version 5.0 (VLFT10GEN SW v5.0) should perform as intended in the specified use conditions.