November 2, 2017

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

Re: K172757
Trade/Device Name: Valleylab FX8 FX Series 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: September 11, 2017
Received: September 13, 2017

Dear Sharon 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 (DICE) 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 (DICE) 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 -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172757

Device Name
Valleylab FX8 FX Series Energy Platform

Indications for Use *(Describe)*
The Valleylab FX8 FX Series Energy Platform is a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.

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.

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6 510(k) Summary

510(k) Summary

Date summary prepared: November 1, 2017

510(k) Submitter/Holder
Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact
Sharon McDermott
Sr. Regulatory Affairs Product Specialist
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Identification of Device

Trade Name:	Valleylab™ FX8 FX Series Energy Platform
Catalog Number:	VLFX8GEN
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI)

Identification of Predicate Device

Trade/Proprietary Name:	Valleylab FT10 Energy Platform
Common/Usual Name:	Electrosurgical Generator
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Class/Panel:	Class II, General and Plastic Surgery
Regulation:	21 CFR 878.4400
Product Code:	GEI
510(k) Submitter / Holder:	Covidien 5920 Longbow Drive Boulder, CO, 80301
Predicate 510(k) #:	K151649, K170170

Identification of Reference Predicate

Trade/Proprietary Name:	**Force FX Generators**
Common/Usual Name:	Electrosurgical Generator
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Class/Panel:	Class II, GEI, 21 CFR 878.4400

510(k) Submitter / Holder:	Covidien 5920 Longbow Drive Boulder, CO, 80301
510(k) #:	K944602, K143161

A reference predicate, Force FX Electrosurgical Generators, (K944602, K143161) was used for comparison testing of the "FX Bipolar" modes included on the subject Valleylab FX8 FX Series Energy Platform.

Substantial Equivalence Overview

The proposed Valleylab FX8 FX Series Energy Platform was compared and found to be substantially equivalent to the predicate Valleylab FT10 Energy Platform. Characteristics identified as important for substantial equivalence comparison purposes are shown in the tables below, and similarities and differences of aspects found to be relevant to the potential impact on safety and performance are discussed in this section. None of the differences raise new questions of safety or effectiveness when compared to the predicate device.

Valleylab FX8 FX Series Energy Platform is used in hospitals and other health care facilities where surgical procedures are carried out.

Valleylab FX8 FX Series Energy Platform can be used with a variety of legally marketed accessories including monopolar and bipolar instruments, footswitches, and return electrode pads. The Valleylab FX8 FX Series Energy Platform connects to electrical mains and operates at an input line frequency of 47-63 Hz.

Principle of Operation

Valleylab FX8 FX Series Energy Platform is a radio-frequency (RF) electrosurgical generator that delivers energy to compatible surgical instruments. The concentration of energy at the tip of the instrument in conjunction with tissue characteristics produces heat. The heating of tissue provides the desired surgical effect (cutting, coagulation, sealing). Variations in the waveform result in the different surgical effects achieved by different modes.

Indications for Use

The Valleylab FX8 FX Series Energy Platform is a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue.

Technological Characteristics

The technological characteristics of the proposed Valleylab FX8 FX Series Energy Platform are the same as the predicate, VLFT10. Both are full-featured general-surgery energy platform. The monopolar and bipolar sections of the generator are isolated outputs that provide the appropriate power for cutting, desiccating, and fulgurating tissue during monopolar and bipolar surgery.

During monopolar electrosurgery, radio frequency (RF) energy exits/enters a monopolar pencil and electrode in high concentration and disperses as it enters/exits the return pad. The concentration of energy at the monopolar pencil in conjunction with tissue characteristics produces heat that provides the desired surgical effect.

Performance Characteristics

Extensive verification and validation activities were successfully completed that establish that the Valleylab FX8 FX Series Energy Platform performs as intended and is substantially equivalent to its predicate, VLFT10. Testing included the following:

- Compliance with Electrical Safety and EMC standards:

IEC 60601-1:2005/A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Edition 3.1
IEC 60601-1-2:2014	Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-2-2:2009	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 5.0

- *Ex vivo* testing using porcine tissue showed comparable performance with regard to thermal effects.
- System verification showed that the Valleylab FX8 FX Series Energy Platform has all required functionality and that it meets system specifications.
- Software verification and validation testing was conducted and documentation provided in accordance with FDA's, *Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices*

The minor differences that were seen during testing are consistent with design changes and do not raise safety or effectiveness concerns.

Clinical Studies

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

Conclusion

Verification and validation testing demonstrates the proposed Valleylab FX8 FX Series Energy Platform is substantially equivalent to the predicate, Valleylab VLFT10 Energy Platform. The two electrosurgical generators have the same intended use and fundamental technology with the exception that the subject platform does not include vessel sealing functionality. The new generator has similar performance when compared to the predicate device. The differences do not raise any new questions of safety and efficacy when compared with the predicate.