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

April 3, 2015

Covidien
Mr. Donald Henton
Regulatory Affairs Manager
5920 Longbow Drive
Boulder, Colorado 80301

Re: K143654
Trade/Device Name: Valleylab™ LS10, LS Series Single Channel Vessel Sealing Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 6, 2015
Received: March 9, 2015

Dear Mr. Henton:

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" (21CFR 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 yours,

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)*
K143654

Device Name
Valleylab™ LS10, LS Series Single Channel Vessel Sealing Generator (VLLS10GEN)

Indications for Use *(Describe)*

The Valleylab LS10, LS Series Single Channel Vessel Sealing Generator is an electrosurgical generator containing LigaSure vessel sealing technology.

The vessel sealing function is indicated for use in sealing (fusing) vessels (including pulmonary) up to and including 7mm in diameter, tissue bundles, and lymphatics during general surgery including, but not limited to surgical specialties such as urologic, vascular, thoracic, gynecologic, plastic and reconstructive, and colorectal.

Refer to each instrument's instructions for use (IFU) for additional indications, warnings, and specific contraindications.

The LigaSure system 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.

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510(k) Summary

Date summary prepared: 12/12/2014

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact

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Regulatory Affairs Manager
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Name of Device

Trade Name:	Valleylab™ LS10, LS Series Single Channel Vessel Sealing Generator
Catalog Numbers:	VLLS10GEN
Common Name:	Bipolar Electrosurgical Vessel Sealing Generator
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, Class II, GEI).

Predicate Device

The Valleylab™ LS10, LS Series Single Channel Vessel Sealing Generator (VLLS10GEN) was compared to and found to be substantially equivalent to the following products of comparable type in commercial distribution:

Trade Name:	ForceTriad™ Electrosurgical Generator
Device Common Name:	Bipolar Electrosurgical Generator
Catalog Number:	ForceTriad
510(k) Number:	K110268 (cleared 05/31/2011)
Manufacturer:	Covidien

Device Description

Valleylab™ LS10, LS Series Single Channel Vessel Sealing Generator (VLLS10GEN) is a bipolar electrosurgical generator with LigaSure™ vessel sealing output mode. The generator is an electrically isolated, microcontroller-based device, incorporating closed-loop control for LigaSure™ mode implemented in the microcontroller firmware. It incorporates tissue sensing circuitry to constantly measure the electrical resistance of the tissue and instantaneously adjust the generator output to maintain the desired power.

The generator is used with compatible LigaSure™ instruments to ligate (seal) and divide (cut) vessels up to and including 7mm, tissue bundles, and lymphatics during the general surgical procedures using radio frequency (RF) energy. When a LigaSure™ instrument is applied to a vessel or tissue bundles, and RF energy is activated by the generator, the collagen and elastin in the tissues are reformed by heat and pressure to fuse vessel walls, thereby forming a permanent seal. The microprocessor within the generator monitors the tissue properties, stops the application of energy, and allows a brief period of cooling before indicating that the seal cycle is complete.

Indications for Use

The Valleylab™ LS10, LS Series Single Channel Vessel Sealing Generator is an electrosurgical generator containing LigaSure™ vessel sealing technology.

The vessel sealing function is indicated for use in sealing (fusing) vessels (including pulmonary) up to and including 7mm in diameter, tissue bundles, and lymphatics during general surgery including, but not limited to surgical specialties such as urologic, vascular, thoracic, gynecologic, plastic and reconstructive, and colorectal.

Refer to each instrument's instructions for use (IFU) for additional indications, warnings, and specific contraindications.

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

Technological Characteristics

Valleylab™ LS10, LS Series Single Channel Vessel Sealing Generator (VLLS10GEN) has the equivalent LigaSure sealing performance with updated technological characteristics including improved electronics and microprocessors for energy delivery, simplified user interface, integrated radio frequency identification (RFID) technology, smaller overall dimensions, and the addition of a USB port as compared to the predicate, ForceTriad™. Valleylab™ LS10 generator incorporates LigaSure™ technology that provides precise energy delivery with electrode pressure on vessels to achieve a complete and permanent vessel seal.

Valleylab™ LS10 generator has one LigaSure™ port in the front panel allowing for connection of a single LigaSure™ instrument, and provides a footswitch port in the rear panel to be used with compatible LigaSure™ single pedal footswitch. It provides visual and audible indicators to indicate the compatibility of instruments/footswitch and shows the status of seal cycle until the seal cycle is complete.

Valleylab™ LS10 generator is compatible with intelligent instruments that include a Radio Frequency Identification (RFID) tag and/or Aztec barcodes in the housing of the instrument cable plug. The RFID module is located above the LigaSure™ port of the generator, and is intended to identify the inserted LigaSure™ instrument and configure the generator with the data included in the RFID tag. The RFID tag on the instrument will be read by the proposed generator prior to scanning the barcode label upon detecting an instrument insertion.

Valleylab™ LS10 generator provides a USB Port used for remote service, data output, and data input. It can be connected with Covidien Valleylab™ Exchange Platform to download the software for the purpose of generator configuration and data exchange.

Performance

Evidence of safety and effectiveness were obtained from bench testing and preclinical testing.

Bench testing to support the intended use of this generator includes:

- Testing in accordance with IEC 60601-1
- Testing in accordance with IEC 60601-2-2
- Testing in accordance with IEC 60601-1-2
- Software verification and validation in accordance with IEC 62304
- Engineering and functional testing including system, mechanical, electrical and general functional testing
- Renal and pulmonary burst pressure
- Thermal profile of the device including maximum external jaw temperature, external jaw cool down time, and maximum shaft temperature

Preclinical testing includes:

- Sealing and dividing vessels up to and including 7 mm
- Ability to achieve hemostasis of tissue, vessels, tissue bundles
- Thermal spread
- Lymphatic burst pressure
- Chronic animal study

Conclusion

The results of the testing demonstrate that the proposed Valleylab™ LS10 generator operated as intended and is substantially equivalent to the predicate generator, ForceTriad™.