November 19, 2018

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

Re: K182772
Trade/Device Names: Valleylab™ Smoke Evacuation Rocker Switch Pencil and Accessories and Valleylab™ Telescoping Smoke Evacuation Rocker Switch Pencil

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 28, 2018
Received: October 1, 2018

Dear Ms. 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
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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Digitally signed by Long H. Chen
Date: 2018.11.19 11:59:35 -05'00'

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
Indications for Use

510(k) Number (if known)
K182772

Device Name
Valleylab™ Smoke Evacuation Rocker Switch Pencil and Accessories and Valleylab™ Telescoping Smoke Evacuation Rocker Switch Pencil

Indications for Use (Describe)
The smoke evacuation rocker switch pencil and telescoping smoke evacuation rocker switch pencil are intended for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

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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510(k) Summary
Date summary prepared: November 13, 2018

510(k) Submitter/Holder
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Contact
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Name of Device
Trade Name: Valleylab™ Smoke Evacuation Rocker Switch Pencil and Accessories and Valleylab™ Telescoping Smoke Evacuation Rocker Switch Pencil
Common Name: Monopolar Electrosurgical Smoke Evacuation Instrument and Accessories
Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR § 878.4400, Class II, GEI)

Predicate Device
Trade Name: Valleylab™ Smoke Evacuation Pencil
Common Name: Monopolar Electrosurgical Smoke Evacuation Instrument
510(k) Number: K103375 (cleared 03/16/2011) by MedTek, dba Buffalo Filter
Manufacturer: Buffalo Filter
Recalls: This device has not been subject to a design-related recall

No reference devices were used in this submission.
Device Description
The Valleylab™ Smoke Evacuation Rocker Switch Pencil family consists of sterile, single-use, hand-held monopolar electrosurgical instruments designed for use with compatible Covidien generators that include monopolar capabilities to cut and coagulate through tissue. They have a standard three-prong monopolar plug. The devices have an integrated smoke capture capability and are included with a default adapter that can aid in the connection to a smoke evacuation system. The adapter can be removed or replaced as needed to fit a variety of smoke evacuation systems. The proposed device family will be provided gamma sterilized. The proposed devices do not contain software.

The pencil family consists of standard and telescoping pencil models and associated accessories. The standard model is designed with a fixed smoke nozzle and electrode length, with the option for use with extender accessories (Valleylab™ Smoke Evacuation Extension Tube) and longer electrodes to access deeper spaces while maintaining smoke evacuation capabilities. The telescoping model has an independently telescoping smoke nozzle and electrode, allowing for a customizable configuration.

Indications for Use
The smoke evacuation rocker switch pencil and telescoping smoke evacuation rocker switch pencil are intended for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Technological Characteristics
The subject device and the predicate devices are based on the following same technological element:

- Monopolar Energy
- Monopolar electrode
- Sterilized, single use
- Integrated smoke capture capability

The following technological differences exist between the subject and predicate devices:

- Sterilization method
- Shelf life
- Physical features and dimensions
- Maximum voltage
- Extended length configurations
- Electrode coating
- Smoke evacuation
**Performance Data**
The following performance data were provided in support of the substantial equivalence determination.

**Biocompatibility**
The biocompatibility evaluation for the Valleylab™ Smoke Evacuation Rocker Switch Pencil family was conducted in accordance with ISO 10993-1, “Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process.” The testing included the following:
- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Hemolysis

The direct patient-contacting materials are: stainless steel and polymers including polycarbonate and ABS.

**Electrical Safety and Electromagnetic Compatibility (EMC)**
Electrical safety testing and EMC testing were conducted on the Valleylab™ Smoke Evacuation Rocker Switch Pencil family. The system complies with relevant portions of the IEC 60601-1 and IEC 60601-2-2 standards for electrical safety and IEC 60601-1-2 standard for EMC.

**Mechanical / Functional Testing**
Mechanical, electrical, and functional testing was carried out to verify that the proposed device family performs as expected and conforms to requirements defined in related design inputs and subsequent product specifications.

**Ex-vivo Monopolar Thermal Effect**
Monopolar ex vivo testing evaluated thermal effect resulting from monopolar energy application across the range of power setting and modes on the proposed devices in comparison to the predicate device. Testing utilized the Force FX™ Electrosurgical Generator Series (K944602), the ForceTriad™ Energy Platform (K051644), the Valleylab™ FT10, FT Series Energy Platform (K151649), and the Valleylab™ FX8, FX Series Energy Platform (K172757). Monopolar thermal effects were evaluated on three different tissue types with three power settings for all three energy modes.

**Pre-Clinical Studies**
This premarket submission does not rely on the assessment of pre-clinical performance data to demonstrate substantial equivalence.

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

**Human Factors and Usability**
The usability engineering process applied to the proposed devices was in compliance with the requirements of IEC 62366 “Medical devices—Application of usability engineering to medical devices.” The process included analysis of user needs and potential use errors followed by testing to demonstrate that representative users can use the instruments safely and correctly.
Summary
Based on the non-clinical performance as documented in the performance testing, the Valleylab™ Smoke Evacuation Rocker Switch Pencil family was found to be as safe and effective as the predicate device.

Conclusions
The comparison of device characteristics and the review of the performance data support the conclusion that the Valleylab™ Smoke Evacuation Rocker Switch Pencil family is substantially equivalent to the predicate device. The devices have the same intended use for their common fundamental technologies. The proposed devices have some design differences that enable them to better perform its indicated use. Testing has demonstrated that these differences do not raise any new questions of safety or effectiveness.