July 1, 2024

Covidien LLC
Miranda Miles
Sr. Regulatory Affairs Specialist
200 Medtronic Dr.
Lafayette, Colorado 80026

Re: K240572
Trade/Device Name: Valleylab™ SM Smoke Management Pencil with Edge™ Blade Electrode, 10' (3m) (VSMP10); Valleylab™ SM Smoke Management Pencil with Edge™ Blade Electrode, 15' (4.6m) (VSMP15); Valleylab™ SM Smoke Management Pencil with Edge™ Blade Electrode, 10' (3m), Non-Sterile Bulk (VSMP10NSB); Valleylab™ SM Smoke Management Extended Nozzle (for use with 4" (100mm) electrode) (VSMEN4); Valleylab™ SM Smoke Management Extended Nozzle (for use with 6.5" (165mm) electrode) (VSMEN6)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 28, 2024
Received: February 29, 2024

Dear Miranda Miles:

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: 2024.07.01 14:47:58 -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)*

K240572

Device Name

Valleylab™ SM Smoke Management Pencil with Edge™ Blade Electrode, 10’ (3m) (VSMP10);
Valleylab™ SM Smoke Management Pencil with Edge™ Blade Electrode, 15’ (4.6m) (VSMP15);
Valleylab™ SM Smoke Management Pencil with Edge™ Blade Electrode, 10’ (3m), Non-Sterile Bulk (VSMP10NSB);
Valleylab™ SM Smoke Management Extended Nozzle (for use with 4” (100mm) electrode) (VSMEN4);
Valleylab™ SM Smoke Management Extended Nozzle (for use with 6.5” (165mm) electrode) (VSMEN6)

Indications for Use *(Describe)*

The Valleylab™ SM Smoke Management Pencil and accessories are designed for general electrosurgical applications, including cutting and coagulation, and for removing surgical 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.

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510(k) Summary

Date: February 28, 2024

510(k) Submitter/Holder

Covidien llc
200 Medtronic Dr
Lafayette, CO 80026

Contact

Miranda Miles, Sr Regulatory Affairs Specialist
Telephone: 800-255-6774
Email: Miranda.r.miles@medtronic.com

Proposed Device

Trade Name:	The Valleylab™ SM Smoke Management Pencil and accessories
Classification Name:	Electrosurgical cutting & coagulation device and accessories (21 CFR 878.4400, Class II, GEI)

Predicate Device

Trade Name:	The Valleylab™ Smoke Evacuation Rocker Switch Pencil and accessories
Classification Name:	Electrosurgical cutting & coagulation device and accessories (21 CFR 878.4400, Class II, GEI)
510(k) Number:	K182772 (cleared 11/19/2018)
Manufacturer:	Covidien llc
Recalls:	None

Device Description

The Valleylab™ SM Smoke Management Pencils are monopolar electrosurgical smoke evacuation pencils intended for cutting and coagulation of tissue while simultaneously removing surgical smoke. The pencils are designed to capture surgical smoke and improve visibility to target tissues, while reducing staff and patient exposure to the hazards of surgical plume. The Valleylab™ SM Smoke Management Extended Nozzle accessories are for use with longer electrodes for deeper access procedures. The predicate device is the Valleylab™ Smoke Evacuation Rocker Switch Pencil cleared under K182772.

The proposed devices are compatible with Covidien electrosurgical generators at a maximum peak voltage 4500 Vpk having a 3-prong connector and smoke evacuators having a 3/8” port. Electrode compatibility includes use with standard 3/32” diameter hex and non-hex electrodes. The pencils are available in 10’ and 15’ tubing/cable lengths models.

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Indications for Use

The Valleylab™ SM Smoke Management Pencil and accessories are designed for general electrosurgical applications, including cutting and coagulation, and for removing surgical 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.

Comparison of Technological Characteristics with the Predicate Device

The proposed Valleylab™ SM Smoke Management Pencil and accessories have the same indications for use with different technological characteristics compared to the predicate. The proposed slimmer pencil body and a swivel connection to a more flexible tubing. The proposed device has different button shapes, lower maximum rated accessory voltage, and expanded electrode compatibility.

Characteristic	Proposed Device(s): Valleylab™ SM Smoke Management Pencils VSMP10, VSMP15, VSMP10NSB, VSMEN4, VSMEN6	Predicate Device(s): Valleylab™ Smoke Evacuation Rocker Switch Pencils SEP5000, SEP5015, SEP5000NSB, SEP5015NSB, SEA50595	Comparison
Classification Regulation	878.4400	878.4400	Same
Class	II	II	Same
Product Code	GEI	GEI	Same
Indications	The Valleylab™ SM Smoke Management Pencil and accessories are designed for general electrosurgical applications, including cutting and coagulation, and for removing surgical 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.	The smoke evacuation rocker switch pencil is designed 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.	Same
Contraindications	None	None	Same
Prescription Use Only	Yes	Yes	Same
Single Use	Yes	Yes	Same
Sterile	Pencil(s) – VSMP10, VSMP15 Nozzle(s) - VSMEN4, VSMEN6	Pencil(s) - SEP5000, SEP5015 Nozzle - SEA50595	Same
Non-sterile	Pencil - VSMP10NSB	Pencil(s)- SEP5000NSB, SEP5015NSB	Same
Sterilization Method	Ethylene Oxide (EO)	Radiation (R)	Different – Differences in Established Category A sterilization methods.
Removable Extended Nozzle	Yes - VSMEN4, VSMEN6	Yes - SEA50595	Same
Instrument Design	Pencil	Pencil	Same
Instrument Dimensions (in)	0.58 x 0.53 x 7.47 in	0.8495 x 0.6430 x 7.50 in	Different – The proposed device is slimmer compared to the predicate device.
Instrument Weight (lbs)	0.280 lbs	0.334 lbs	Different – The proposed device is lighter compared to the predicate device.
Smoke Nozzle Diameter at tip (in)	0.320 in	0.430 in	Different – The proposed nozzles are narrower compared to the predicate device.
Cord Length	10 ft and 15 ft	10 ft and 15 ft	Same
Energy Activation Type	Handswitching - Button	Handswitching - Rocker Switch	Different – Differences in handswitching energy button type.
Energy Type	Monopolar Electrosurgery	Monopolar Electrosurgery	Same
ESU Compatibility / Rated Accessory Voltage (V_{pk})	4500 V_{pk}	5550 V_{pk}	Different – Differences in maximum V_{pk} compatibility.
ESU Connector	3-prong plug	3-prong plug	Same
Electrode Length (in)	2.5 in	2.5 in	Same

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Characteristic	Proposed Device(s): Valleylab™ SM Smoke Management Pencils VSMP10, VSMP15, VSMP10NSB, VSMEN4, VSMEN6	Predicate Device(s): Valleylab™ Smoke Evacuation Rocker Switch Pencils SEP5000, SEP5015, SEP5000NSB, SEP5015NSB, SEA50595	Comparison
Electrode Diameter (in)	Standard 3/32 in.	Standard 3/32 in	Same
Electrode Interface	Non-hex and hex locking	Non-hex locking	Different – The proposed device can also accept hex locking interface electrodes.
Electrode and Nozzle Configuration	Fixed	Fixed	Same
Pencil to Tubing Joint	Swivel	Ball	Different – Differences in joint type.
Patient Contacting Materials Compatible per ISO 10993-1	Yes	Yes	Same

All differences have been evaluated using the substantial equivalence decision tree in the FDA guidance, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification (2014)." The evaluation and test results support a conclusion of substantial equivalence.

Performance Testing

The following test performance data were provided in support of the substantial equivalence determination of the Valleylab™ SM Smoke Management Pencil and accessories.

Sterilization and Shelf-Life

The Valleylab™ SM Smoke Management Pencil and accessories met the acceptance criteria for sterilization by ethylene oxide (EO) to sterility assurance level 10^{-6} in accordance with the applicable validation standards ISO 11135, ISO 11737-1, ISO 11737-2 and ISO 10993-7. Product packaging was designed and validated in accordance with packaging standards ISO 11607-1, ISO 11607-2, ASTM D4169. In addition, the Valleylab™ SM Smoke Management Pencils are labeled for a 4-year shelf-life, whereas the Valleylab™ SM Smoke Management Extended Nozzles are labeled for a 5-year shelf-life in accordance with accelerated aging methods per ASTM F1980.

Biocompatibility

The Valleylab™ SM Smoke Management Pencil and accessories met the requirements of biocompatibility standard ISO 10993-1 for the following endpoints: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, and material-mediated pyrogenicity.

Software

The Valleylab™ SM Smoke Management Pencil does not contain software.

Electromagnetic Compatibility and Electrical Safety

The Valleylab™ SM Smoke Management Pencil met the applicable clauses of electromagnetic compatibility standard IEC 60601-1-2 and electrical safety standards IEC 60601-1, and IEC 60601-2-2.

Performance Testing – Bench

The Valleylab™ SM Smoke Management Pencil and accessories met the device requirements for mechanical, functional, reliability and ex vivo thermal tissue effect testing.

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Performance Testing – Animal

The Valleylab™ SM Smoke Management Pencil did not undergo animal testing.

Performance Testing – Clinical

The Valleylab™ SM Smoke Management Pencil did not undergo clinical studies.

Usability/Human Factors

The Valleylab™ SM Smoke Management Pencil and accessories demonstrated safe and effective use for the intended users, intended use, and use environments according to methods in IEC 60601-1-6 and IEC 62366-1.

Conclusion

The differences between the Valleylab™ SM Smoke Management Pencil and accessories relative to the predicate device did not raise different questions of safety or efficacy. The results of comparative testing to the predicate device and standards-based testing support the conclusion that the proposed device is substantially equivalent to the predicate device.