April 15, 2021

Covidien LLC
Miranda Miles
Associate Regulatory Affairs Specialist
5920 Longbow Drive
Boulder, Colorado 80301

Re: K210338
Trade/Device Name: Edge Insulated Blade Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 4, 2021
Received: February 5, 2021

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 (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 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 and Part 809); 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/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 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 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: 2021.04.15 16:19:33 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210338

Device Name
Edge™ Insulated Blade Electrode

Indications for Use *(Describe)*
The Edge™ Insulated Blade Electrode is intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

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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COVIDIEN

510(k) Summary

Date summary prepared: April 15, 2021

510(k) Submitter/Holder

Covidien
5920 Longbow Drive
Boulder, CO 80301

Contact

Miranda Miles
Associate Regulatory Affairs Specialist
Telephone: 303-530-6205
Email: miranda.r.miles@medtronic.com

Subject Device

Trade Name:	Edge™ Insulated Blade Electrode
Common Name:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI)

Predicate Device

Trade Name:	Megadyne™ E-Z Clean™ Electrosurgical Electrode
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Class II, GEI)
510(k) Number:	K081791
Recalls:	This device has not been subject to a design-related recall

No reference devices were used in this submission.

Device Description

The Edge™ Insulated Blade Electrode (E1455G) is a sterile, single-use, monopolar electrode intended to conduct radiofrequency (RF) current. It is a coated stainless-steel electrode blade with insulation. It is compatible with electrosurgical pencils that have a 0.093" insertion diameter or commonly referred to as a standard 3/32" insertion diameter, this includes the Covidien Valleylab™ Rocker Switch Pencil Family (SEP5000, SEP5015) cleared in K182772.

Indications for Use

The Edge™ Insulated Blade Electrode is intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.

Comparison of Technological Characteristics with the Predicate Device

The Edge™ Insulated Blade Electrode (E1455G) device is compared to the predicate device Megadyne™ E-Z Clean™ Electrosurgical Electrode (0012M), as cleared under K081791 in Table 5-1.

Table 5-1. Technological and performance characteristics comparison of subject device to predicate device.

Characteristic	**Subject Device Edge™ Insulated Blade Electrode (E1455G)**	**Predicate Device Megadyne™ E-Z Clean™ Electrosurgical Electrode (0012M) [K081791]**	**Results (compared to predicate)**
Classification Regulation	878.4400	878.4400	Same
Class	II	II	Same
Product Code	GEI	GEI	Same
Indications for Use	The Edge™ Insulated Blade Electrode is intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.	E-Z™ Clean electrosurgical electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization. Some tip configurations have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the generator's Advanced Cutting Effect (ACE) mode.	Equivalent - The subject device is not indicated for use with Advanced Cutting Effect (ACE) mode. Differences do not change the intended use of the device.
Contraindications	None	None	Same
Single Use	Yes	Yes	Same
Sterile	Yes	Yes	Same
Electrode Material	Stainless steel	Stainless steel	Equivalent
Coating	Yes	Yes	Equivalent
Insulation	Yes	Yes	Same
Length	2.5”	2.5”	Same
Compatibility	0.093” shaft insertion diameter	0.093” shaft insertion diameter	Same
Sterilization	Ethylene oxide (EO)	Ethylene oxide (EO)	Same
Energy Type	Monopolar radiofrequency	Monopolar radiofrequency	Same

Characteristic	Subject Device Edge™ Insulated Blade Electrode (E1455G)	Predicate Device Megadyne™ E-Z Clean™ Electrosurgical Electrode (0012M) [K081791]	Results (compared to predicate)
Rated Accessory Voltage	<4500V_{pk}	<10.8kV	Rated accessory voltage does not affect electrical safety or performance.

Performance Testing

Biocompatibility

The biocompatibility evaluation for the Edge™ Insulated Blade Electrode was conducted in accordance with ISO 10993-1. The testing included the following:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

The direct tissue contacting materials include stainless steel, silicone and polymer insulation. The subject device complies with the relevant clauses of ISO 10993-1.

Electromagnetic Compatibility (EMC) and Electrical Safety

Electromagnetic compatibility (EMC) and electrical safety were evaluated on the Edge™ Insulated Blade Electrode. The subject device complies with relevant clauses of the IEC 60601-1 and IEC 60601-2-2 standards for electrical safety and IEC 60601-1-2 standard for EMC.

Mechanical/Functional Bench Testing

Mechanical, electrical, and functional testing were carried out to verify that the subject device performs as expected and conform to requirements defined in related design inputs and product specifications.

Ex vivo Thermal Effect

Monopolar *ex vivo* testing evaluated thermal effect resulting from monopolar energy application across a range of power setting and modes on different tissue types. The subject device demonstrated substantial equivalence to the predicate device.

Conclusion

The comparison of device characteristics and the review of the performance data support the conclusion that the Edge™ Insulated Blade Electrode is substantially equivalent to the predicate

device. The Edge™ Insulated Blade Electrode (E1455G) was found to be as safe and effective as the predicate device Megadyne™ E-Z Clean Electrosurgical Electrode (0012M).