CnC Technologies
℅ Wooseok Jeong
Regulatory Affairs Consultant
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
Korea, South

February 3, 2023

Re: K220996
Trade/Device Name: Duoblade
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 25, 2022
Received: April 4, 2022

Dear Wooseok Jeong:

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); 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,

Colin K. Chen -S

for

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)*
K220996

Device Name
Duoblade

Indications for Use *(Describe)*
The Duoblade is intended for general electrosurgical applications, including cutting and coagulation, and (Models: DB1SEP, DB1SEP-H, DB1SEP-T, DB1SEP-TH) for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

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

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 1, 2023

1. Applicant / Submission Sponsor

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2. Submission Correspondent

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3. Device Identification

Trade/Proprietary Name: Duoblade
Common Name: Electrosurgical Cutting and Coagulation Device and Accessories
Classification Regulation: 21CFR 878.4400
Product Code: GEI
Device Class: 2

4. Predicate Devices

	Predicate Device 1
Manufacturer	Covidien
Device Name	Valleylab™ Smoke Evacuation Rocker Switch Pencil and Accessories and Valleylab™ Telescoping Smoke Evacuation Rocker Switch Pencil
510(k) number	K182772

5. Description

The Electrosurgical Cutting and Coagulation Device and Accessories (Model: Duoblade) is a single-use, monopolar RF device. It is designed to be used with the qualified Generator as part of the Surgery System. It can be operated with the integrated hand switch or a qualified Footswitch. The Duoblade consists of a single blade and telescoping shaft that can be configured in both standard and extended length. The finger grip also incorporates a suction lumen for the evacuation of smoke and fluids.

The models of Duoblade are identified according to with/without a suction function (removing smoke).

- Suction function (Removing smoke): DB1SEP, DB1SEP-H, DB1SEP-T, DB1SEP-TH
- No Suction function (No removing smoke): DB1SP, DB1SP-H, DB1SP-T, DB1SP-TH

6. Indications for use

The Duoblade is intended for general electrosurgical applications, including cutting and coagulation, and (Models: DB1SEP, DB1SEP-H, DB1SEP-T, DB1SEP-TH) for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

7. Substantial Equivalence

The Electrosurgical Cutting and Coagulation Device and Accessories (Model: Duoblade) is substantially equivalent to the predicate device, Valleylab™ Smoke Evacuation Rocker Switch Pencil and Accessories and Valleylab™ Telescoping Smoke Evacuation Rocker Switch Pencil (K182772, Covidien). The following comparison table is presented to demonstrate substantial equivalence.

-	Subject Device	Predicate Device 1 (PD1)	Comparison
Manufacturer	CnC Technologies, Inc.	Covidien	-
Device Name	Duoblade	Valleylab™ Smoke Evacuation Rocker Switch Pencil and Accessories and Valleylab™ Telescoping Smoke Evacuation Rocker Switch Pencil	-
510(k) number	K220996	K182772	-
Product Code	GEI	GEI	Same
Regulatory Class	2	2	Same
Indications for Use	The Duoblade is intended for general electrosurgical applications, including cutting and coagulation, and (Models: DB1SEP, DB1SEP-H, DB1SEP-T, DB1SEP-TH) for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.	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.	Same
Mechanism of Action / Principle of operation	RF Monopolar Energy	RF Monopolar Energy	Same
Maximum rated accessory voltage	4,500 Vpk	5,550 Vpk	Rated accessory voltage does not affect electrical safety or performance.
Sterilization	EtO	Gamma	Different
Biocompatibility	External communicating device <24 hours, tested to ISO 10993-1	External communicating device <24 hours, tested to ISO 10993-1	Same
Blade Material	Coated Aluminum	Stainless Steel	Different
Integrated Suction	Yes	Yes	Same
Blade Dimensions (Diameter x Length)	3.0 x 11.0 mm	2.6 x 17.0 mm	Different

Technical Characteristics

1) Same Points between subject device and predicate device

Item	Description
Product Code	The product code of the subject device is “GEI”. It is the same product code both subject device and predicate device.
Regulatory Class	The regulatory classification of the subject device is “Class II”. It is the same classification both subject device and predicate device.
Indications for Use	The Indications for Use is same.
Mechanism of Action / Principle of operation	The subject device uses RF Monopolar Energy. It is the same both subject device and predicate device.
Biocompatibility	The biocompatibility characteristics are same both subject device and predicate device. The subject device has passed the biocompatibility test.
Integrated Suction	The subject device has suction function. It is same with the predicate device.

2) Different Points between subject device and predicate device

Item	Description
510(k) number	K number does not influence the safety and the performance of the subject device as well as does not influence substantial equivalence between the subject device the predicate device.
Maximum rated accessory voltage	The maximum rated accessory voltage of the subject device is “4,500 Vpk” and predicate device is “5,550 Vpk”. But the rated accessory voltage does not affect electrical safety or performance. We conducted the basic safety and essential performance according to the IEC 60601-2-2 for subject device and the thermal effects on tissue test comparing the subject device and predicate device. The testing results show that these differences do not raise different questions of safety and effectiveness. (The related test reports are attached in this submission).
Sterilization	The sterilization method of the subject device is “EtO Sterilization” and predicate device is “Gamma Sterilization”. We conducted sterilization validation for subject device, the results show that these differences do not raise different questions of safety and effectiveness. (The sterilization validation report is attached in this submission).
Blade Material	The subject device is aluminum and the predicate device is stainless steel. We conducted biocompatibility test according to the ISO 10993-1, the basic safety and essential performance according to the IEC 60601-2-2 for subject device and the thermal effects on tissue test comparing the subject device and predicate device. The testing results show that these differences do not raise different questions of safety and effectiveness. (The related test reports are attached in this submission).
Blade Dimensions (Diameter x Length)	The blade dimension of the subject device is 3.0 x 11.0 mm (Diameter x Length), predicate device is 2.6 x 17.0 mm. Although there are differences in dimensions, we conducted the basic safety and essential performance according to the IEC 60601-2-2 for subject device and the thermal effects on tissue test comparing the subject device and predicate device. The testing results show that these differences do not raise different questions of safety and effectiveness. (The related test reports are attached in this submission).

8. Biocompatibility

The biocompatibility tests of patient indirect contact part (Blade, FEP Tube, Blade Adaptor) were performed in accordance with the following FDA recognized standards.

- ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- FDA Guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

9. Sterility

The Duoblade is provided sterile, intended to be single-use. This product is EO-Sterilization in accordance with ISO 11135.

The sterilization test was performed in accordance with the following FDA recognized standards.

- ISO 11135:2014: Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical device
- ISO 10993-7:2008: Biological evaluation of medical device-Part7 Ethylene oxide sterilization residuals

10. Shelf Life

The shelf life of the subject device is 3 years.

The validation report of the subject device shows that the difference in the shelf life does not influence the quality performance of the packaging based on the result of confirmation of physical and chemical stability and effectiveness through accelerated aging test of the samples. The validation report is provided in this submission file.

The shelf life method has been validated in accordance with the following standards.

- ASTM F1980-16: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F88/F88M-15: Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 11607-1:2019: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

11. Electromagnetic Compatibility (EMC) and Electrical Safety

The Electromagnetic Compatibility (EMC) and Electrical Safety tests were performed in accordance with the following FDA recognized standards.

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-2-2:2017, 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
- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

12. Performance Test - Thermal effects on tissue

The purpose of this study was to compare penetrating thermal tissue damage/spread associated with the subject device and predicate device using the fresh extirpated porcine muscle, liver and kidney model.

In results of histopathological examination, evidence of wound healing and thermal burn in incision site was evaluated. Although there were no significant differences between the positive control device and test device administered sites on every group, in liver under some conditions and kidney under most conditions, the midline depth and width of the test device application sites showed low tendency compared to positive control device application sites. Therefore, positive control and test article administered group assumed to have no difference in wound coagulation necrosis of incision sites.

In conclusion, the test device was considered to have the equivalent penetrative thermal tissue damage/spread characteristics compared to the positive control device.

13. Clinical Test

No clinical studies were considered for this submission.

14. Conclusion

In comparing between the subject device and the predicate device, there are the same product code, regulatory classification, indications for use, principle of operation, biocompatibility, integrated suction. Although the maximum rated accessory voltage, sterilization, blade material and blade dimensions are difference, the related reports are supported to the safety and effectiveness of the subject device.

Therefore, we conclude that the different characteristics do not raise different questions of safety and effectiveness, and thus the subject device is substantially equivalent to the predicate device.