August 11, 2025

CnC Technologies
% Jeong Mi Won
Official Correspondent
CTI co.,Ltd
A-1712, 43, Iljik-ro
Gwangmyeong-si, Gyeonggi-do 14353
Korea, South

Re: K252211
Trade/Device Name: Duoblade Plus SE (DB1EP, DB1EP-T, DB1EP-H, DB1EP-TH); Duoblade Prime (DB1P, DB1P-T, DB1P-H, DB1P-TH)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 11, 2025
Received: July 15, 2025

Dear Jeong Mi Won:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2025.08.11 16:42:36 -04'00'

James Jang, Ph.D.
Acting 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)*

- K252211

Device Name

Duoblade Plus SE (DB1EP, DB1EP-T, DB1EP-H, DB1EP-TH);
Duoblade Prime (DB1P, DB1P-T, DB1P-H, DB1P-TH)

Indications for Use *(Describe)*

The Duoblade Plus SE (Models: DB1EP, DB1EP-T, DB1EP-H, DB1EP-TH), and Duoblade Prime (Models: DB1P, DB1P-T, DB1P-H, DB1P-TH) are intended for general electrosurgical applications, including cutting and coagulation. These models are designed without shaft extension functionalities. The Model: DB1EP, DB1EP -T, DB1EP-H, DB1EP-TH are compatible with the smoke evacuation system, 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 special 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 11, 2025

1. Applicant / Submission Sponsor

CnC Technologies
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2. Submission Correspondent

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3. Device Identification

Trade/Proprietary Name: Duoblade Plus SE, Duoblade Prime
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	CnC Technologies
Device Name	Duoblade
510(k) number	K220996

5. Description

The Electrosurgical Cutting and Coagulation Device and Accessories (Model: Duoblade Plus SE, Duoblade Prime) is a single-use, monopolar RF device designed to be used with a qualified Generator as part of the Surgery System. It uses high-frequency energy (RF Monopolar Energy) to generate heat for tissue cutting and

coagulation. It can be operated using the integrated hand switch or a qualified Footswitch. The device's design simplifies functionality by excluding shaft extension features.
The models of Duoblade Plus SE and Duoblade Prime are identified according to with/without a suction function (removing smoke), and a swivel function.

- Suction & swivel function (Duoblade Plus SE): DB1EP, DB1EP-T, DB1EP-H, DB1EP-TH
- No Suction & swivel function (Duoblade Prime): DB1P, DB1P-T, DB1P-H, DB1P-TH

The scope of the submission only includes the addition of model without functions, such as swivel function, shaft extension function and appearance change for marketing purpose.

6. Indications for use

The Duoblade Plus SE (Models: DB1EP, DB1EP-T, DB1EP-H, DB1EP-TH), and Duoblade Prime (Models: DB1P, DB1P-T, DB1P-H, DB1P-TH) are intended for general electrosurgical applications, including cutting and coagulation. These models are designed without shaft extension functionalities. The Model: DB1EP, DB1EP -T, DB1EP-H, DB1EP-TH are compatible with the smoke evacuation system, 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 Plus SE, Duoblade Prime) is substantially equivalent to the predicate device, Duoblade (K220996, CnC Technologies). The following comparison table is presented to demonstrate substantial equivalence.

-	Subject Device		Predicate Device 1 (PD1)	Comparison
Manufacturer	CnC Technologies		CnC Technologies	Same
Device Name	Duoblade Plus SE	Duoblade Prime	Duoblade	Same
510(k) number	-		K220996	-
Product Code	GEI		GEI	Same
Regulatory Class	2		2	Same
Indications for Use	The Duoblade Plus SE (Models: DB1EP, DB1EP-T, DB1EP-H, DB1EP-TH), and Duoblade Prime (Models: DB1P, DB1P-T, DB1P-H, DB1P-TH) are intended for general electrosurgical applications, including cutting and coagulation. These models are designed without shaft extension functionalities. The Model: DB1EP, DB1EP -T, DB1EP-H, DB1EP-TH are compatible with the smoke evacuation system, removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.		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.	Same
Mechanism of Action / Principle of operation	RF Monopolar Energy		RF Monopolar Energy	Same
Sterilization	EtO		EtO	Same
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		Coated Aluminum	Same
Integrated Suction	DB1EP, DB1EP-T, DB1EP-H, DB1EP-TH: Yes	DB1P, DB1P-T, DB1P-H, DB1P-TH: No	DB1SEP, DB1SEP-T, DB1SEP-H, DB1SEP-TH: Yes DB1SP, DB1SP-T, DB1SP-H, DB1SP-TH: No	Same
Blade Dimension	3.0 x 11.0 mm		3.0 x 11.0 mm	Same

(Diameter x Length)					
Shaft Extension	Excluded		All model included		Different
Swivel	DB1EP, DB1EP-T, DB1EP-H, DB1EP-TH: Yes	DB1P, DB1P-T, DB1P-H, DB1P-TH: No	All model included		Different
Main Body Dimension	**DB1EP** Main body: 20.8 cm [8.2 inch] Cord: 300 cm [118 inch] length	**DB1P** Main body: 19 cm [7.5 inch] Cord: 300 cm [118 inch] length	**DB1SEP** Unextended: 21 cm [8.3 inch] length Extended: 27.5 cm [10.8 inch] length Cord: 300 cm [118 inch] length	**DB1SP** Unextended: 21 cm [8.3 inch] length Extended: 27.5 cm [10.8 inch] length Cord: 300 cm [118 inch] length	Different
Color of main body and cable	Orange		Gray		Different
Shape of Blade adaptor	Gradually widening conical shaft, improving visual alignment and grip ergonomics		Uniform cylindrical shaft with constant diameter		Different
Labeling	User manual (IFU) update due to the design changes		N/A		Different

1) Same Points between subject device and predicate device

Item	Description
Product Code	The product code of the subject device is “GEI”. It has 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.
Indication for Use	The intended use remains the same as that of the predicate device.
Mechanism of Action / Principle of operation	The subject device uses RF Monopolar Energy. It is the same as both subject device and predicate device.
Sterilization	The sterilization method of the subject device is “EtO Sterilization”. It is the same sterilization method both subject device and predicate device.

Biocompatibility	The biocompatibility characteristics are the same as both subject device and predicate device. The predicate device has passed the biocompatibility test. There is no change in raw materials between the predicate device and the subject device.
Integrated Suction	The subject device includes models with and without the smoke evacuation function. Similarly, the predicate device also has models with and without the smoke evacuation function, leading to the conclusion that they are substantially equivalent.

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 and the predicate device.
Shaft extension	The removal of the shaft extension does not affect the intended use or the overall function of the device. The mechanical design change does not alter the safety or performance characteristics, as the core functionality of the device remains unchanged.
Swivel function	The removal of the swivel function does not impact the safety or performance of the device. The device still performs its intended function, with no degradation in usability or functionality, ensuring that the subject device remains substantially equivalent to the predicate device.
Main Body Dimension	The change in main body dimensions is minimal and does not affect the device's performance or safety. The new dimensions do not interfere with the device’s ability to function as intended and fall within the specifications of the predicate device.
Color of main body and cable	The color change of the main body and cable is purely for marketing purpose and does not affect the mechanical or electrical performance of the device. The material properties and safety features remain consistent with the predicate device, ensuring no impact on safety or performance.
Shape of Blade adaptor	The change in the shape of the blade adaptor does not influence the overall function or safety of the device. It is a design modification that does not affect the interaction of the device with the user or its intended clinical use and thus does not affect substantial equivalence.
Labeling	This labeling update does not impact substantial equivalence between the subject device and the predicate device, as it is a non-functional update for compliance purposes only.

8. Biocompatibility

The biocompatibility tests for the patient indirect contact parts (Blade, FEP Tube, Blade Adaptor) were conducted in accordance with the FDA-recognized standards applied to the predicate device (K220996).

- 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"

The materials have not changed for these devices since their original clearance, in which full biocompatibility information was provided.

9. Sterility

The predicate device (Duoblade, K220996) 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

The sterilization method and condition has not changed since the original clearance; therefore, no additional testing was needed.

10. Shelf Life

The shelf life of the subject device is 3 years.

The validation report of the predicate 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

The product and packaging materials as well as the sterilization method has not changed since the original clearance, therefore no additional testing was needed.

11. Electrical Safety

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

- AAMI ES60601-1:2005/AMD1:2012, AAMI ES60601-1:2005/AMD2:2021 (IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020), Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-2:2017/AMD1:2023, 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+A1:21522020, Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances -Requirements and tests

Basic safety, and essential performance tests for electrical safety were conducted to demonstrate substantial equivalence to the predicate device and to ensure safe electrical operation.

12. Thermal effects on tissue

The thermal effects of a subject device are the same as the predicate device.

The subject device is used with an FDA approved electrosurgical unit, and the rated voltage is the same as the predicate device. Also, the shape and dimensions for a blade of subject device are same as the predicate device.

13. Performance Test _ Non-Clinical 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 in 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 (predicate device, K220996) was considered to have the equivalent penetrative thermal tissue damage/spread characteristics compared to the positive control device.

The thermal effects of a subject device are the same as the predicate device.

The subject device is used with an FDA approved electrosurgical unit, and the rated voltage is the same as the predicate device. Also, the shape and dimensions for a blade of subject device are same as the predicate device.

14. Clinical Test

No clinical studies were considered for this submission.

15. 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 different, 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.