June 6, 2025

CnS Medical Co., Ltd.
% Kim Jiwon
Regulatory Affairs Consultant
Kmc
#1709, G-Plus Tower, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
Korea, South

Re: K242907
Trade/Device Name: DELPHI System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 7, 2025
Received: May 7, 2025

Dear Kim Jiwon:

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: 2025.06.06 14:44:01 -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)*

K242907

Device Name

DELPHI System

Indications for Use *(Describe)*

DELPHI System is indicated for coagulation and ablation of tissue and hemostasis of blood vessels during arthroscopic surgery. DELPHI System is designed for exclusive use with DELPHI PLUS or DISCORE bipolar electrode.

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

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

Date: September 10, 2024

1. Applicant / Submission Sponsor

CnS Medical Co.,Ltd.
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2. Submission Correspondent

JIWON KIM (Consultant, KMC, Inc.), JeongKeun KIM (Consultant, KMC, Inc)
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3. Device Identification

Trade/Proprietary Name: DELPHI System
Common Name: Electrosurgical, Cutting & Coagulation & Accessories
Classification Regulation: 21CFR 878.4400
Product Code: GEI
Device Class: 2

4. Predicate Devices

	Predicate Device #1
Manufacturer	ArthroCare Corporation
Device Name	Ambient HipVac 50 Wand with integrated Finger Switches, RF20000 COBLATION System, WEREWOLF COBLATION system, WEREWOLF+COBLATION System
510(k) number	K220563

5. Description

DELPHI System is a bipolar, high radiofrequency electrosurgical device designed for coagulation and ablation of tissue and hemostasis during arthroscopic surgery. DELPHI system consists of DELPHI II (Generator), power cable, Mode Footswitch, output Footswitch, DELPHI PLUS (Electrodes) and DISCORE (Electrode). The DELPHI II is an electrically isolated radiofrequency generator designed to deliver power for soft tissue ablation (vaporization) and coagulation procedures in arthroscopic surgery. The DELPHI II offers the operator the flexibility to choose from a range of functional modes using the front panel set-up options. These modes include PETTIE MODE and GRANDE MODE for tissue ablation and coagulation. DELPHI PLUS and DISCORE bipolar electrode is a foot-controlled sterile, single-use electrosurgical electrode intended to deliver radiofrequency energy for coagulation and ablation of tissue and hemostasis during arthroscopic surgery in conjunction with DELPHI System.

6. Indications for use

DELPHI System is indicated for coagulation and ablation of tissue and hemostasis of blood vessels during arthroscopic surgery. DELPHI System is designed for exclusive use with DELHI PLUS or DISCORE bipolar electrodes. DO NOT use other manufacture's or brand of electrodes with DELPHI System.

7. Substantial Equivalence

The Electrosurgical device system is substantially equivalent to the predicate device, Ambient HipVac 50 Wand with Integrated Finger Switches and RF20000 COBLATION System (K220563, ArthroCare Corporation). The following comparison table is presented to demonstrate substantial equivalence.

-	Subject Device	Predicate Device	Comparison
Manufacturer	CNS medical Co.,Ltd	ArthroCare Corporation	-
Device Name	DELPHI System	Ambient HipVac 50 Wand with Integrated Finger Switches, RF20000 COBLATION System, WEREWOLF COBLATION System, WEREWOLF+ COBLATION System	-
510(k) Number	None	K220563	-
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	Same
Regulation Name	Electrosurgical devices and accessories	Electrosurgical devices and accessories	Same
Regulatory Class	II	II	Same
Product Code	GEI	GEI	Same
Indications for Use	DELPHI System is indicated for coagulation and ablation of tissue and	The Ambient HipVac 50 Wand with Integrated Finger Switches is	Same

	hemostasis of blood vessels during arthroscopic surgery. DELPHI System is designed for exclusive use with DELPHI PLUS or DISCORE bipolar electrode.	indicated for the resection and ablation of soft tissue, and hemostasis of blood vessels less than 1 mm (via coagulation) in the following arthroscopic and orthoscopic procedures.	
Rated Input	100~120 / 220~240V 50/60 Hz	100 – 240V~, 50/60 Hz	Same
Output Frequency	100KHz	100KHz	Same
Type of protection against electric shock	Class I	Class I	Same
Degree of protection against electric shock of applied part	Type BF	Type BF	Same
Ablation Output Voltage	100-275.68 Vrms	100-314 Vrms	Similar[1]
Coagulation Output Voltage	63-100 Vrms	65-100 Vrms	Similar[2]
Output Control Mechanism	Wired Foot switch	Wired or Wireless foot pedal	Same
Weight	9.86Kg	<5Kg	-
Controller waveforms	Square wave	Square wave	Same
Output Voltage	Set point: 0-275 Vrms Coag: 63, 100 Vrms	Set point: 0-320 Vrms Coag: 65,98 Vrms	Similar[3]
Software Program	DELPHI II PGM, Ver 1.0	Software for Quantum II, V 2.03	-
Wand Specifications / Features			
Shaft Length	DP Model: 110mm, 130mm, 150mm, 280mm DPS Model: 150, 280mm DD Model: 150, 240, 380mm	176 mm	Similar[4]
Handle Length	DP Model: 180mm DPS Model: 180mm DD Model: 146mm	141.75 mm	Similar[5]
Distal Bend Angle	15°, 45°, 90°	50°	Similar[6]
Outer Diameter of Shaft	DP Model: 4.0mm, 2.3mm DPS Model: 4.0mm DD Model: 2.1mm	4.6mm	Similar[7]
Sterilization	EO gas	Radiation	Different[8]
Electrical Safety EMC	IEC 60601-2-2 IEC 60601-1 IEC 60601-1-2 compliant	IEC 60601-2-2 compliant	Same
Suction and/or Irrigation	Yes	Yes	Same
Packaged Sterile	Yes	Yes	Same
Tyvek Packaging/adhesive	Yes	Yes	Same
Operates in Saline	Yes	Yes	Same

Environment			
Bipolar / Mono-polar	Bipolar	Bipolar	Same
Use Limiting Feature	Yes	Yes	Same
Software in Wand	No	No	Same
Single Use Disposable	Yes	Yes	Same

Technical Characteristics

1) Same Points between subject device and predicate device

Item	Description
Indications for Use	The indications for use is same between subject device and predicate device.
Rated Input	The rated input of subject device is “100~120 / 200~240V, 50/60 Hz”. It is same with the predicate device.
Output Frequency	The subject device is 100KHz. It is same with the predicate device.
Type of protection against electric shock	The subject device is class I. It is same with the predicate device.
Degree of protection against electric shock of applied part	The subject device is Type BF. It is same with the predicate device.
Output Control Mechanism	The subject device is Wired Foot switch. It is same with the predicate device.
IEC 60601-1	The subject device complies with IEC 60601-1. It is same with the predicate device.
IEC 60601-1-2	The subject device complies with IEC 60601-1-2. It is same with the predicate device.
IEC 60601-2-2	The subject device complies with IEC 60601-1-2. It is same with the predicate device.
ISO 14971	The subject device complies with ISO 14971. It is same with the predicate device.

2) Different Points between subject device and predicate device

Item	Description
[1] Ablation Output Voltage	The output of the subject device falls within the output range of the predicate device, and all data points are within the tolerance.
[2] Coagulation Output Voltage	The output of the subject device falls within the output range of the predicate device, and all data points are within the tolerance.
[3] Output Voltage	The output of the subject device falls within the output range of the predicate device, and all data points are within the tolerance.
[4] Shaft Length	More available shaft lengths are designed for different clinical application, it will not impact device safety and effectiveness.
[5] Handle Length	More available Handle lengths are designed for different clinical application, it will not impact device safety and effectiveness.
[6] Distal Bend Angle	More available distal bend angles are designed for different clinical application, it will not impact device safety and effectiveness.
[7] Outer Diameter of	More available outer diameter of shaft are designed for different clinical application, it will not impact device safety and effectiveness.

Item	Description
Shaft	
[8] **Sterilization**	Both the predicate device and the subject device are sterilized as single-use product. But the sterilization method used does not affect the efficacy or safety or the devices.

8. 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, Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances -Requirements and tests

9. Clinical Test

No clinical studies were considered for this submission.

10. Conclusion

In comparing between the subject device and the predicate device, there are the same Indications for Use, rated input, output frequency, protection rating of the applied part, and compliance with IEC 60601-1, IEC 60601-2-2, IEC 60601-1-2 and ISO 14971.

Although the output voltage differs slightly, it is within the tolerance and falls within the output the output range of the predicate device.

While the hand length and sterilization method differ, they do not raise further questions regarding safety and effectiveness.

Therefore, the subject device is substantially equivalent to the predicate device.