May 16, 2025

Cellah Medical Co., Ltd.
Priscilla Chung
1513, 75-24, Gasan digital 1-ro, Geumcheon-gu
(Gasandong, Gasna IS BIS Tower)
Seoul, 08589
Korea, South

Re: K243176
Trade/Device Name: BLESSING System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI, OUH
Dated: April 15, 2025
Received: April 15, 2025

Dear Priscilla Chung:

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: 2025.05.16 14:02:24 -04'00'

James Jang
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)*

K243176

Device Name

BLESSING System

Indications for Use *(Describe)*

The BLESSING System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(K243176)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: May 15, 2025

1. 510K Applicant / Submitter:

Cellah Medical Co., Ltd.
1513, 75-24, Gasan digital 1-ro, Geumcheon-gu, Seoul (Gasandong, Gasna IS BIS Tower).
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Tel: +82-2-6956-3881

2. Submission Contact Person

LK Consulting Group USA, Inc.
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3. Device

- Proprietary Name: BLESSING System
- Common Name: Electrosurgical coagulation device and accessories
- Regulation Name: Electrosurgical cutting and coagulation device and accessories
- Classification: 21 CFR 878.4400
- Product Code: GEI

4. Predicate Device

POTENZA (K201685) Jeisys Medical, Inc.

5. Description:

The device is used for coagulation through high-frequency current and consists of a main body, three types of handpieces, a handpiece stand, an electrode, a neutral (counter) electrode, a counter electrode connection cable, a foot switch, and a power cord, all controlled by software. It works on the principle that skin tissue coagulates due to heat generated by the load or contact resistance when high-frequency (RF) energy is applied to the tissue.

6. Indications for Use

The BLESSING System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

7. Substantial Equivalence Discussion:

The subject device is substantially equivalent to the predicate device, POTENZA (K201685) made by Jeisys Medical, Inc. The indications for use and the fundamental technology is the same.
There are minor differences in specifications, however, we determine that it does not raise a question in safety and effectiveness based on the information submitted here in. The detailed substantial equivalence discussion is provide in the table below.

	Subject Device	**Predicate Device**	
Device Name	**BLESSING System**	**POTENZA**	**Comparison**
Manufacturer	Cellah Medical,Co.Ltd	Jeisys Medical, Inc.	-
510(k) #	K243176	K201685	-
Indication for Use	The BLESSING System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis	The POTENZA is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis	Same
System Type	Bipolar/ Monopolar RF	Bipolar/ Monopolar RF	Same
Frequency	1Mhz/2Mhz	1Mhz/2Mhz	Same
Max Output Power	30W (Load 200Ω)	50W (Load 200Ω)	The maximum output power of the proposed device is different from that of the predicate devices. However, the maximum output power of the proposed BLESSING System is lower than that of the predicate devices and falls within the maximum output power range. Therefore, this difference does not substantially affect the equivalence in terms of safety and effectiveness.
Voltage output	0~77.5V	0~100V	The Voltage output of the proposed device is different from that of the predicate devices. However, the Voltage output of the proposed BLESSING System is lower than that of the predicate devices and falls within the Voltage output range. Therefore, this difference does not substantially affect the equivalence in terms of safety and effectiveness.
Operation Mode	Level Mode Manual Mode	Microneedle Fractional RF	The names of the operating modes are determined by the manufacturer, and although the names are different, the way of operation and use are the same. The BLESSING system operates in two

			modes for the convenience of the user, and these differences do not affect the equivalence in terms of safety and effectiveness.
Treatment Duration (Time)	10ms~990ms	5~990ms	The treatment period (time) of the proposed device is different from that of the predicate devices. However, the treatment period (time) of the proposed BLESSING system is within the range of the treatment period (time) of the predicate devices. Therefore, this difference does not affect the equivalence in terms of safety and effectiveness.
Tip	DRS Handpiece Tip D-N10 VRS Handpiece Tip V-I49 V-N49 V-I25 V-N25 V-I16 V-N16 V-CI49 ORS Handpiece Tip O-I1	N-49 TIP, I-49 TIP, N-25 TIP, I-25 TIP, N-16 TIP, I-16 TIP, C21-2 TIP, C21-1 TIP, P21-TIP, C9- TIP, P1-08, A1-12, A1-15	The overall tip configuration is the same. The number of needles ranges from 1 to 49, which falls within the range of needle quantities for the predicate devices, so there are no safety issues. In the case of the D-N10 tip, the design allows it to enter the skin diagonally, but this does not pose any issues with its usage or safety. Therefore, these differences do not affect equivalence in terms of safety and effectiveness.
Connected handpiece	DRS Handpiece/ VRS Handpiece/ ORS Handpiece	Motor Handpiece,/ AC Handpiece	The names of the "connected handpieces" vary by manufacturer, but their operating mechanisms are the same, so this does not affect equivalence in terms of safety and effectiveness. -Motor handpieces work the same way as DRS handpieces and VRS handpieces. -AC handpieces work the same way as ORS handpieces.
Treatment time	10min~15min	10min~15min	Same
Intensity	0 ~ 10 LEVEL (1 STEP)	1~10 Level.	Same
Needle Diameter	DRS Handpiece Tip Thickness: 0.28mm VRS Handpiece Tip Thickness: 0.28mm ORS Handpiece Tip Thickness: 0.33mm	0.2mm (200 micrometers)	The needle specifications are determined by the manufacturer, and although the gauge specifications are different, safety has been ensured through hemolysis tests and intradermal reaction tests. Therefore, these differences do not affect equivalence in terms of safety and effectiveness.
Weight	40kg	12.5kg	The proposed BLESSING system is a stand-alone product, so a heavier case does not affect the practical equivalence in terms of safety and effectiveness.
Dimension	440 mm (W) x 510 mm	503.2 mm (W) x	The proposed BLESSING system is a

	(L) x 1565 mm (H)	365.6mm (L) x 316mm (H)	stand product, so even if it is larger than the predicate devices, it does not affect the substantial equivalence in terms of safety and effectiveness.
Input Voltage	100-240VAC, 50/60Hz, 180VA	100-240V, 50/60Hz, 500VA	The input voltage of the proposed device is equivalent to that of the predicted device (100-240V, 50/60Hz), but the VA is different. However, the input voltage of the proposed BLESSING system (180VA) is lower than that of the predicted device (500VA) and is within the input voltage range. Therefore, this difference does not significantly affect the equivalence in terms of safety and effectiveness.
Foot Switch	Yes	Yes	Same
Tip Sterilization Method	EO Gas	EO Gas	Same
Number of Usage	Single use	Single use	Same

8. Performance Tests (Non-clinical)

- The EMC and electrical safety testing were conducted on the BLESSING System in accordance with the following standards.

No	Test Item	Test Standard
1	EMC Test Report	IEC 60601-1-2:2014/ AMD1:2020
2	Safety Test Report	IEC 60601-1:2005 + AMD1:2012 + AMD2:2020
3	Safety Test Report (Particular requirements)	IEC 60601-2-2:2017 + AMD1:2023
4	Usability Test Report	IEC 60601-1-6:2010/ AMD2:2020

- Biocompatibility testing was performed on the tip of the handpiece with the following standards.
  - ISO10993-5:2009 Cytotoxicity Test
  - ISO10993-10:2021 Skin Sensitization Test
  - ISO10993-11:2017 Skin Irritation Test
  - ISO10993-11:2017 Acute Systemic Toxicity Test
  - USP 151-2022 Pyrogen Test
  - ISO 10993-4: 2017 Hemolysis Test

- Cleaning Validation, Packaging (Primary adhesion) Process Validation, EO Sterilization Validation, and Shelf-Life tests were performed on the subject device.

- Software Validation Test
- Performance Test per IEC 60601-2-2
- Additional Performance Tests
  - Output Accuracy
  - Frequency Accuracy
  - Impedance Measurement Accuracy and Range
  - HO Count Accuracy
  - Needle Depth
  - Motor Speed (IMPACT test)

The test results of non-clinical tests performed on the subject device supported that it is substantially equivalent to the predicate devices despite the differences.

9. Conclusions:

Based on the information provided in this premarket notification, Cellah Medical Co., Ltd. concludes that the BLESSING System is substantially equivalent to the predicate device as described herein in.