November 26, 2024

Viol Co. Ltd
Sugun Lee
CEO
C-609 Bundang Technopark C, 744 Pangyo-ro, Bundang-gu,
Seongnam-si, Gyeonggi-do
Seoul,
Korea, South

Re: K240897
Trade/Device Name: CELLINEW
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 30, 2024
Received: October 31, 2024

Dear Sugun Lee:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.11.26 16:29:49 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240897

Device Name

Cellinew

Indications for Use *(Describe)*

Cellinew is indicated 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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510(K) Summary
CELLINEW
K240897

Applicant	Viol Co., Ltd.
Address	C-609 Bundang Technopark C, 744 Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do Seoul, South Korea
Contact Person	Oskar (Sugun) Lee
Contact Information	Telephone : 070-7954-1388 Cellphone : +82-10-2388-7739 ceo@skingrab.co.kr
Preparation Date	October 31, 2024
Device Trade Name	CELLINEW
Classification Name	Electrosurgical cutting and coagulation
Common Name	RF Electrosurgical Device
Regulation Number	878.4400
Product Code	GEI
Regulatory Class	II
Legally Marketed Predicate Device	Density (K230663) Jeisys Medical Incorporated

Device Description:
The CELLINEW generates radiofrequency(RF) energy by means of high RF at 6.78Mhz. The RF energy is delivered through the skin into the target tissue via a handpiece equipped with an electrode tip. As the RF energy passes through the tissue, it generates an electrothermal reaction with is capable of coagulation the tissue. In detail, the main body uses the “reverse thermal gradient” principle to deliver RF energy, and thus, heat is generated and selective coagulation occurs while cooling the epidermis, resulting in denaturation and contraction of collagen fibers.

The CELLINEW Device is a non-invasive device for coagulation using high frequency current. The device consists of a main body, handpiece, two disposable electrodes, a neutral electrode, neutral electrode cable, foot switch(optional) and power cord, and is controlled by software.

Indications for use:
Cellinew is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

Device Comparison—Indications for Use:

Subject Device (CELLINEW)	Predicate Device (Density K230663)	Comparison
CELLINEW is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	Density is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	Same

Device Comparison – Technical Specifications:

Specification	CELLINEW (Subject Device)	Jeisys Density (K230663)	Comparison
Output energy type	Radiofrequency	Radiofrequency	Same
User Interface	Color touch panel	Color touch panel	Same
Operating Frequency	6.78MHz	6.78MHz	Same
Max power	Up to 400W	400W	Same
Electrode Tips	0.25cm^2, 4cm^2	0.25cm^2, 4cm^2, 16cm^2	Same (the Cellinew does not include the 16cm^2 tip that the Density has.)
Coolant Solution	Cryogen	Cryogen	Same
Temperature Range	65~75℃	65~75℃	Same
RF Time	0-1050ms	50 ~ 800 ms	Different. The RF time of the subject device is marginally higher than the predicate, but it does not impact the safety or effectiveness of the device.
Impedance	75 - 400 Ω	75 - 400 Ω	Same
Style of Electrode Tip	Monopolar only	Monopolar, Bipolar	Different. The Cellinew only operates in monopolar.

Electrical Safety and Electromagnetic Compatibility

The Electrical Safety and Electromagnetic compatibility tests were performed in accordance with the following standards.

- IEC 60601-1: 2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-2-2: 2017/AMD2:2020 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of Radio frequency surgical equipment and Radio frequency.
- IEC 60601-1-2: 2014/AMD1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Biocompatibility

- 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: 2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices – Part 23:Test for Intracutaneous Reactivity
- ISO 10993-11:2017, Biological evaluation of medical devices – Part 11:Test for Acute Systemic toxicity
- ISO 10993-11:2017, Biological evaluation of medical devices – Part 11:Test for Material Mediated Pyrogenicity

Biocompatibility Tests were performed in accordance with FDA standards and all patient contacting materials were determined to be biocompatible.

Software and Risk Management

- IEC 62304:2006+A1:2015; Medical Device – Software Life Cycle Processes
  Software verification and validation testing was conducted, and documentation provided in accordance with FDA's Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices.
- EN ISO 14971:2019+A11:2021; Medical Devices – Application of Risk Management To Medical Devices

Performance Testing – Performance testing was conducted to demonstrate the accuracy of RF frequency and output power, RF time, and impedance measuring. Thermal testing was performed on porcine skin to demonstrate the device's ability to coagulate tissue. Tests were performed with both tips at all power levels and demonstrated a desired clinical effect.

Clinical Evidence – No clinical studies were conducted as part of this submission.

Conclusion

CELLINEW shares the same indications for use, mode of operation, and overall design as the predicate device. The differences between the systems are small and do not have any impact on safety or efficacy. The predicate device has three sizes of electrodes whereas the CELLINEW has two. The predicate functions in both monopolar and bipolar modes while the CELLINEW has only a monopolar function. There are slight differences in the RF duration but they are not large enough to impact the performance of the device. The CELLINEW and the predicate device can therefore be considered substantially equivalent.