May 23, 2024

Chungwoo Co., Ltd.
Su Jin Lee
Regulatory Affair Manager
614, 2, Gasadigital 1-ro
Guemcheon-gu, Seoul 13201
Korea, South

Re: K233120
Trade/Device Name: CWM-930S
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 27, 2023
Received: September 27, 2023

Dear Su Jin 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.

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: 2024.05.23 11:24:41 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233120

Device Name
CWM-930S Radio Frequency Therapy System

Indications for Use *(Describe)*
This device is intended for use in dermatologic and general surgical procedures for electro coagulation.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

614, 2, Gasandigital1-ro, Geumcheon-gu, Seoul, Republic of Korea
TEL: +82 2-2027-2200 FAX: +82 2-2027-2207

K233120

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

May 22, 2024

2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: Chungwoo Co., Ltd.
- Address: 614, 2, Gasandigital1-ro, Geumcheon-gu, Seoul, Republic of Korea
- Contact Name: Su Jin LEE
- Telephone No.: +82-2-2027-2200
- Fax No.: +82-2-2027-2207
- Email Address: cwra3@mycw.co.kr

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Common name: Radio Frequency Therapy System
Trade name: CWM-930S

Classification Description	21 CFR Section	Product Code
Electrosurgical, Cutting and Coagulation and Accessories	878.4400	GEI

As stated in 21 CFR, parts 878.4400, this generic type of device has been classified as Class II.

614, 2, Gasandigital1-ro, Geumcheon-gu, Seoul, Republic of Korea
TEL: +82 2-2027-2200 FAX: +82 2-2027-2207

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate device 1

- 510(k) Number: K210084
- Applicant: Hironic Co., Ltd
- Classification Name: electrosurgical, cutting & coagulation & accessories
- Trade Name: SILKRO

Predicate device 2

- 510(k) Number: K193070
- Applicant: ShenB Co Ltd.
- Classification Name: electrosurgical, cutting & coagulation & accessories
- Trade Name: VIVACE Electrosurgical System

5. Description of the Device [21 CFR 807.92(a)(4)]

This device is a Fractional RF Surgical Unit with Sterile Micro Needle, which is composed of the main device (generator and user interface display, handpiece, foot switch, neutral electrode, and bipolar and monopolar microneedle electrodes. It is designed for applying radiofrequency therapy with microneedles, which coagulates skin tissue using 1 MHz or 2 MHz radiofrequency energy delivered from the generator to the microneedles. A Bipolar Handpiece suction filter is also available for use to remove unwanted debris from the skin application site and safeguarding the equipment by preventing foreign substances from entering during use.

6. Indications for Use [21 CFR 807.92(a)(5)]

This device is intended for use in dermatologic and general surgical procedures for electro coagulation.

614, 2, Gasandigital1-ro, Geumcheon-gu, Seoul, Republic of Korea
TEL: +82 2-2027-2200 FAX: +82 2-2027-2207

7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between the CWM-930S and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics.

	Proposed Device	Predicate Device 1	Predicate Device 2
K Number	-	K210084	K193070
Manufacturer	Chungwoo Co., Ltd.	Hironic Co., Ltd	ShenB Co Ltd.
Model	CWM-930S	SILKRO	VIVACE Electrosurgical Device
Intended Use	This device is intended for use in dermatologic and general surgical procedures for electro coagulation.	This device is intended for use in dermatologic and general surgical procedures for electro coagulation.	The VIVACE Electrosurgical System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis and the percutaneous treatment of facial wrinkles for use with Fitzpatrick Skin Type I to Skin Type V when using the 1MHz setting. The 2MHz setting has not been evaluated for use in the percutaneous treatment of facial wrinkles and is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
Mode of operation	Bipolar Handpiece + Micro needle electrodes, Monopolar	Bipolar Handpiece + Micro needle electrodes, Monopolar	Bipolar Handpiece + Micro needle electrodes
Operating Frequency	1MHz, 2MHz	2MHz	1 MHz, 2 MHz
Rated Input	AC 100- 240V,50/60Hz	AC 100- 240V,50/60Hz	AC 120V 50/60 Hz
Output	1Mhz : 35W±20% (500Ω)	25W ± 20%, 500Ω	1MHz : 36W±10% (load resistance 500Ω)

614, 2, Gasandigital1-ro, Geumcheon-gu, Seoul, Republic of Korea
TEL: +82 2-2027-2200 FAX: +82 2-2027-2207

	Proposed Device	Predicate Device 1	Predicate Device 2
	2Mhz : 25W±20% (500Ω)		2MHz : 23.3 W (load resistance 500Ω)
RF Intensity	1 ~ 10Level	1 ~ 10 Level	1-10 Level
RF Duration	10ms~900ms	50 ms ~ 950 ms	100ms-800ms (100ms increments)
Treatment Time	5 ~ 15 min	5 ~ 15 min	-
Needle insert depth	Bipolar : 0.5mm~3.5mm(14pin, 25pin, 49pin) / 0.5mm~7.0mm(36pin) ±15% / Adjustment unit 0.1mm monopolar : 0.5mm~5.0mm (0.1mm step)	Bipolar : 0.5 ~ 3.5 mm(0.1 step) monopolar : 1.2, 1.5, 1.8 mm	0.5 ~ 3.5mm (0.1mm step)
Number of pins	Bipolar : RF Microneedle 14pin, 25pin,36pin, 49pin Momopolar : 1pin	Bipolar : RF Microneedle 25pin, 49pin Momopolar : 1pin	36 needle electrode
Needle application range	1pin(1.0 x 1.0mm), 25Pin, 49Pin(7.8 x 7.8mm), 14pin(7.8 x 2.0mm), 36pin(11x11mm)	25pin(8x8mm), 49mm(12x12mm)	-
Sterilization	EO Gas	EO Gas	Sterility Assurance Level (SAL) of 10-6
Biocompatibility tested	Yes	Yes	Yes

614, 2, Gasandigital1-ro, Geumcheon-gu, Seoul, Republic of Korea
TEL: +82 2-2027-2200 FAX: +82 2-2027-2207

Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Electrical Safety, Electromagnetic Compatibility Testing

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

Standard (Edition)	Standard Title
IEC 60601-1:2005/AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
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

2) Software Validation

The CWM-930S contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.

The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on June 14, 2023.

3) Biocompatibility

Part	**Material**	**Patient Contact**	**Duration of Contact by ISO 10993-1**	**Bio-compatibility**
Cap,Electrode(needle and coating)	SUS	Intact Skin	Limited (< 24 hours)	Yes
Neutral Electrode	- Hydrogel - Cloth - Aluminum Film - Transparent Film - Loctite Dura-Tak 129a	Intact Skin	Limited (< 24 hours)	Yes

614, 2, Gasandigital1-ro, Geumcheon-gu, Seoul, Republic of Korea
TEL: +82 2-2027-2200 FAX: +82 2-2027-2207

- Sterilization, Shelf-life Testing

  Ethylene Oxide Sterilization Validation Test: ISO 11135:2014/Amd 1:2018, Sterilization of health care products -- Ethylene oxide -- Requirements for development, validation and routine control of a sterilization process for medical devices

4) Performance Testing

- **Performance test**

The purpose of testing is to validate the performance of this device and ensure that the performance effectiveness of this device is substantially equivalent to predicate device.

- Output characteristics by load resistance
- Frequency
- Amplitude
- Duty cycle
- Crest factor

- **Thermal effect**

Ex vivo animal testing using porcine abdominal skin was also conducted to obtain histological data of values for depth and zone of coagulation and thermal damage immediately post treatment. The treatment was performed at the intensity(power) low, mid, high. Based on this animal test, it was confirmed through mechanical and histological evaluation that micro needle can affect tissue by thermal effect of each output condition.

The results of the tests show that CWM-930 and predicate devices show similar performance in regards to the Thermal effect. Therefore, this study concludes that the CWM-930 is equivalent to the predicate device VIVACE and SILKRO.

Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Chungwoo Co., Ltd. concludes that the CWM-930S is substantially equivalent to and is as safe and effective as the predicate devices as described herein.