June 24, 2024

Hironic Co., Ltd.
Gwijin Lee
Section Chief
19F, U-TOWER, 767, Sinsu-Ro, Suji-Gu
Yongin-Si, Gyeonggi-do 16827
Korea, South

Re: K233123
Trade/Device Name: SILKRO
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 4, 2024
Received: June 4, 2024

Dear Gwijin 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: 2024.06.24 08:49:08 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K233123

Device Name
SILKRO

Indications for Use *(Describe)*
The SILKRO with RM, RN, RC, RV, PS handpieces is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.
The SILKRO with RN handpieces is intended for the removal and destruction of skin lesions and coagulation of tissue.

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 510(k) Safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information - 807.92(a)(1)

Applicant	Hironic Co., Ltd.
Address	19F, U-TOWER, 767, Sinsu-ro, Suji-gu, Yongin-si, Gyeonggi-do, 16827, Republic of Korea
Phone Number	+82-31-525-7000
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Preparation Date	Sep 27th, 2023

Date 510(k) summary prepared: June 21, 2024

2. Device Name and Code - 807.92(a)(2)

Trade/Device Name	SILKRO
Common Name	Electrosurgical System
Classification Name	Electrosurgical cutting and coagulation device and accessories
Product Code	GEI
Regulation Number	21 CFR 878.4400
Regulatory Class	II
Review Panel	General & Plastic Surgery (ODE)

3. Legally marketed device(s) to which equivalence is claimed - 807.92(a)(3)

Predicate Devices 1	K210084 Applicant: Hironic Co., Ltd. Trade/Device Name: SILKRO Regulation Number: 21 CFR 878.4400 Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories Regulatory Class: Class II Product Code: GEI
Predicate Devices 2	K201738 Applicant: Cartessa Aesthetics Trade/Device Name: SubNovii Advanced Plasma Technology Regulation Number: 21 CFR 878.4400 Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories Regulatory Class: Class II Product Code: GEI

4. Device Description - 807.92(a)(4)

This device is an instrument used for tissue coagulation by means of high-frequency current. It consists of the main unit, five handpieces, GP Cable, foot switch, LCD touch screen, ground pad and power cable.

The SILKRO has two operating modes: monopolar mode and bipolar mode. In the monopolar mode, RF energy flows from the main unit and a patient loop is formed by pairing the active electrode tip with the neutral electrode pad. Heat is not generated in the neutral electrode pad due to its low contact resistance, but heat is generated in the active electrode tip which has higher contact resistance. The higher contact resistance heats up the tissue resulting in coagulation. In the bipolar mode, RF energy is delivered between adjacent needles in the electrode tip without use of the neutral electrode pad. The user can select the mode and adjust parameters through the touch screen user interface of electrosurgical device.

RF(HF) energy is delivered to the target tissue using a handpiece (RM, RN, RC, RV, PS) and electrode tip, the tip being placed in light contact with the epidermis and the handpiece being held at right angles to the target tissue. As the RF(HF) energy passes through the skin, it generates an electro RF reaction which is capable of coagulating the tissue.

- Electrosurgical Unit - Main body
- Five different handpieces
- Neutral electrode pad and neutral electrode pad cable, cleared under K092761
- Handpiece stands
- Foot switch
- Power cord

5. Indication for Use - 807.92(a)(5)

The SILKRO with RM, RN, RC, RV, PS handpieces is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.
The SILKRO with RN handpiece is intended for the removal and destruction of skin lesions and coagulation of tissue.

6. Summary of the Technological Characteristics of the Device Compared to the Predicate - 807.92(a)(6)
(1) Predicate Device 1

	Proposed Device	Predicate Device 1
510(k) Number	Pending	K210084
Manufacturer	Hironic Co., Ltd.	Hironic Co., Ltd.
Trade/Device Name	SILKRO	SILKRO
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Indication for use	The SILKRO with RM, RN, RC, RV, PS handpieces is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis. The SILKRO with RN handpiece is intended for the removal and destruction of skin lesions and coagulation of tissue.	This device is intended for use in dermatologic and general surgical procedures for electro-coagulation.
Output energy type	Radio Frequency	Radio Frequency
User interface	Color Touch Panel	Color Touch Panel
Operating Frequency	2MHz	2MHz
Rated Input	100-240VAC, 50/60Hz	100-240VAC, 50/60Hz
Max. Power	RM Handpiece: 20.520 W ± 20 %, 500 Ω RN Handpiece: 7.587 W ± 20 %, 500 Ω	RM Handpiece: 25W ± 20%, 500Ω RN Handpiece: 7.5W ± 20%, 500Ω RC Handpiece: 34 W ± 20%, 500Ω RV Handpiece: 18 W ± 20%, 500Ω

	RC Handpiece: 33.754 W ± 20 %, 500 Ω RV Handpiece: 18.354 W ± 20 %, 500 Ω	
RF Intensity	1 ~ 10 Level	1 ~ 10 Level
RF Duration	RM Handpiece: 50 ms ~ 950 ms RN Handpiece: 50 ms ~ 1000 ms	RM Handpiece: 50 ms ~ 950 ms RN Handpiece: 100 ms ~ 1000 ms
Needle Insert Depth	RM Handpiece with RF Micro Needle Tip: 0.5 ~ 3.5 mm RN Handpiece with A-FIT RF Needle Tip: 1.2/1.5/1.8 mm	RM Handpiece with RF Micro Needle Tip: 0.5 ~ 3.5 mm RN Handpiece with A-FIT RF Needle Tip: 1.2/1.5/1.8 mm
Repetition	RM Handpiece: 0.2/0.5/0.8/1.0/2.0 sec, Single	RM Handpiece: 0.2/0.5/0.8/1.0/2.0 sec, Single
Mode of Operation	RM Handpiece: Bipolar Type RN, RC, RV Handpiece: Monopolar Type	RM Handpiece: Bipolar Type RN, RC, RV Handpiece: Monopolar Type
Electrode(Needle) Type	RF Micro Needle Tip for RM Handpiece: 25 pin, 49 pin A-FIT RF Needle Tip for RN Handpiece: 1 pin	RF Micro Needle Tip for RM Handpiece: 25 pin, 49 pin A-FIT RF Needle Tip for RN Handpiece: 1 pin
Single Use	RF Micro Needle Tip for RM Handpiece A-FIT RF Needle Tip for RN Handpiece	RF Micro Needle Tip for RM Handpiece A-FIT RF Needle Tip for RN Handpiece
Sterilization	EO Gas	EO Gas

(2) Predicate Device 2

	Proposed Device	Predicate Device 2
510(k) Number	Pending	K201738
Manufacturer	Hironic Co., Ltd.	Cartessa Aesthetics
Trade/Device Name	SILKRO	SubNovii Advanced Plasma Technology
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Indications for Use	The SILKRO with PS RN handpieces is intended for the removal and destruction of skin lesions and coagulation of tissue.	The SubNovii is intended for the removal and destruction of skin lesions and coagulation of tissue.
Mode of Operation	RN Handpiece Radiofrequency energy ionizes the air creating a Plasma stream	Plasma Radiofrequency energy ionizes the air creating a Plasma stream
Output	Monopolar	Monopolar
Power Supply	100-240VAC, 50/60Hz	110-250 VAC 50/60 Hz
Frequency	2 MHz	40 kHz
Max Power Output	7.587W @ 500Ω	5W
Electrical Safety Standards	Complies with IEC 60601-1, IEC 60601-1-2, IEC60601-2-2	Complies with IEC 60601-1, IEC 60601-1-2

7. Non-clinical tests submitted - 807.92(b)(1)

- IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- 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 is evaluated in accordance with the FDA-recognized consensus standard
- IEC 60601-1-6:2010 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability is evaluated in accordance with the FDA-recognized consensus standard
- IEC 62304:2006 Medical device software – Software life cycle processes is evaluated according to the FDA-recognized consensus standard
- IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices is evaluated in accordance with the FDA-recognized consensus standard
- ISO 14971:2019 Medical devices – Application of risk management to medical devices
- ex vivo animal testing using micropig models was also conducted to obtain histological data of values for depth and zone of coagulation and thermal damage immediately post treatment; 10 days 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 RM, RN, RV, RC, PS handpieces can affect tissue by thermal effect of each output condition.

8. Clinical tests submitted - 807.92(b)(2)

No clinical test was performed.

9. Conclusions drawn from clinical and non-clinical tests submitted

The SILKRO is similar to its predicate devices in regards to indication for use and technological characteristics. The non-clinical test data for proposed device, including biocompatibility, bench testing, hardware and software documentation shows that the device performs substantially equivalent in terms of safety and effectiveness to identified predicate devices for proposed indications for use.