June 3, 2022

Hironic Co., Ltd
℅ Sang Hwa Myung
Regulatory Affair Consultant
E&M
D-1474, 230, Simin-daero, Dongan-gu
Anyang-si, Gyeonggi-do 14067
Republic of Korea

Re: K210084
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: January 7, 2022
Received: January 10, 2022

Dear Sang Hwa Myung:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210084

Device Name
SILKRO

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.

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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.

K210084

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

Applicant	Hironic Co., Ltd.
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Preparation Date	Jan 07, 2022

Date 510(k) summary prepared: June 01, 2022

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	K170325 Applicant: ILOODA CO., LTD Trade/Device Name: Secret RF Regulation Number: 21 CFR 878.4400 Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories Regulatory Class: Class II Product Code: GEI, OUH
Reference Devices 1	K182355 Applicant: ILOODA CO., LTD Trade/Device Name: Secret RF Smartcure Applicator Regulation Number: 21 CFR 878.4400 Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories Regulatory Class: Class II Product Code: GEI, OUH
Reference Device 2	K201685 Applicant: Jeisys Medical Inc. Trade/Device Name: Potenza 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, Four handpieces, GP Cable, foot switch, LCD touchscreen, 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 the electrosurgical device.

RF(HF) energy is delivered to the target tissue using a handpiece (RM, RN, RC, RV) 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 HF energy passes through the skin, it generates an electro RF reaction, which is capable of coagulating the tissue.

- Electrosurgical Unit - Main body
- Four different handpieces (motor)
- 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)

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

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

(1) Predicate device

	Proposed Device	Predicate Device
510(k) Number	Pending	K170325
Manufacturer	Hironic Co., Ltd.	ILOODA CO., LTD
Trade/Device Name	SILKRO	Secret RF
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Indication for use	This device is intended for use in dermatologic and general surgical procedures for electro-coagulation.	Secret RF is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.
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	25W ± 20%, 500Ω	25W ± 20%, 500Ω
RF Intensity	1 ~ 10 Level	1 ~ 10 Level
RF Duration	50 ms ~ 950 ms	50 ms ~ 950 ms
Treatment Time	5 ~ 15 min	10 ~ 15 min

	(Recommended)	(Recommended)
Needle insert depth	0.5 ~ 3.5 mm(0.1 step)	0.5 ~ 3.5mm (0.1 step)
Repetition	0.2/0.5/0.8/1.0/2.0 sec/Single	0.2 / 0.5 / 1 / 2 sec / Single
Mode of operation	Bipolar type	Bipolar type
Electrode(Needle) type	RF Microneedle 25pin, 49pin	RF Micro needle 25pin, 49pin
Sterilization	EO Gas	EO Gas

Information provided in these 510(k) submissions shows that SILKRO are substantially equivalent to the predicate device(K170325) in terms of indication for use, performance that related with technological characteristics. SILKRO Treatment time is recommendation between 5 to 15 min and it is within range of predicate device(K17025)'s treatment time.

(2) Reference Device 1

	Proposed Device	Reference Device 1
510(k) Number	Pending	K182355
Manufacturer	Hironic Co., Ltd.	ILOODA CO., LTD
Trade/Device Name	SILKRO	Secret RF Smartcure Applicator
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Indication for use	This device is intended for use in dermatologic and general surgical procedures for electro-coagulation.	Secret RF Smartcure Applicator is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis
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
Power output	7.5 W±20%, 500Ω	45W±20%, 500Ω
RF Duration	100 ms ~ 1000 ms	100 ms ~ 3000 ms
Treatment Time	10~ 15 minutes	10~ 15 minutes
Needle insert depth	1.2, 1.5, 1.8 mm	0.8/1.25/1.5/ 2.0 mm
Mode of operation	Monopolar	Monopolar
Electrode(Needle) type	1 pin type	1 pin Type
Single Use	Single Use	Single Use
Sterilization	EO Gas	EO Gas

Information provided in these 510(k) submissions shows that SILKRO electrosurgical system's RN handpiece is substantially equivalent to the Reference device 1(K182355) in terms of indication for use, and performance that related with technological characteristics. RF duration is not exact same values but our duration is within in range of reference device's duration value.

(3) Reference Device 2

	Proposed Device	Reference Device 2
510(k) Number	Pending	K201685
Manufacturer	Hironic Co., Ltd.	Jeisys Medical Inc
Trade/Device Name	SILKRO	Potenza
Classification Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories

Indication for use	This device is intended for use in dermatologic and general surgical procedures for electro-coagulation.	Potenza is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.
Output energy type	Radio Frequency	Radio Frequency
Operating Frequency	2MHz	2MHz
Power output	Maximum 40 W ±20%,	Maximum 50W±20%,
Treatment Time	10 ~ 15 min	10 ~ 15 min
Treatment Activation	Touch screen, Foot switch, Neutral electrode pad and neutral electrode pad cable, cleared under K092761.	Touch screen, Foot switch, Neutral electrode pad and neutral electrode pad cable, cleared under K092761.
Mode of operation	Monopolar	Monopolar

Information provide in these 510(k) submissions shows that SILKRO electrosurgical system's Electrosurgical Unit part, Bipolar and monopolar operating mode, output frequency of 2MHz, ***same*** as for the reference device. Also, treatment time, treatment activation with operation mode, same as for the reference device.

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

-. Basic safety and essential performance of the SILKRO is evaluated in accordance with IEC 60601-1:2012.

-. Effect to the device by electromagnetic disturbances is evaluated in accordance with the FDA-recognized consensus standard, IEC 60601-1-2:2014.

-. 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 60601-2-2,

-. General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability is evaluated in accordance with the FDA-recognized consensus standard, IEC 60601-1-6:2013.

-. Risk management is recorded in the reference of ISO 14971:2007.

-. The software for SILKRO is verified and validated in accordance with its moderate level of concern. Software life cycle processes are evaluated according to the FDA-recognized consensus standard, IEC 62304:2006.

-. Application of usability engineering to medical devices is evaluated in accordance with IEC 62366:2007.

- 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 handpieces can affect tissue by thermal effect of each output condition.

8. Biocompatibility

Hironic Co., Ltd performed biocompatibility testing for the contact part of each of handpiece's tips. FDA's "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process", June 6, 2016.
SILKRO skin contact materials (Applied part that touched patients' skin permanently within 24 hours) were evaluated according to ISO 10993-1. The results of this test confirmed that materials met the biocompatibility requirements. Biocompatibility testing including cytotoxicity, sensitization, oral

mucosal irritation was completed according to the following standards: ISO 10993-1 Biological Evaluation of Medical Devices –Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process ISO 10993-5 Biological Evaluation of Medical Devices – Part 5 Cytotoxicity ISO 10993-10 Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization ISO 10993-12 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials.

Each tip are external communicating devices which come into contact with tissue for a limited period of time, i.e., less than 24 hours.

9. **Sterilization and shelf life**

-. Sterilization

The RM Micro Needle tips (RMT-I25, RMT-N25, RMT-I49, RMT-N49) and RN Needle tips are subject to Ethylene Oxide (EO) sterilization.

EO sterilization residual testing for the RM Micro Needle tips (RMT-I25, RMT-N25, RMT-I49, RMT-N49) and RN Needle tips according to ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals to acceptance criteria as specified in the standard. According to ISO 11135:2014, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices, the sterility assurance level (SAL) is 10^{-6}.

-. **Shelf life**

Hironic Co., Ltd performed shelf-life testing to establish three years shelf-life based on 97-days accelerated aging in accordance with the following standards to the acceptance criteria as specified in the standard:

- ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices – Accelerated Aging
- ASTM F1929-15: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration – Packaging Test
- ASTM F88/F88M: Standard Test Method for Seal Strength of Flexible Barrier Materials

-. Packaging

RMT-I49 is packed in PET+Steril Paper. To keeping the sterility of the product is important for this shelf life study. The test based on ASTM F1980-16, Accelerated aging theory.

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

SILKRO device has same indications for use and similar design and technological characteristics as the predicate device. The differences between the subject devices and the predicate device do not raise new questions of safety or efficacy. Results of performance testing demonstrated substantial equivalence of the subject device to the predicate. Therefore, the subject device is as safe and effective as previously cleared predicate device for the proposed intended use.