October 19, 2023

Shenzhenshi Sincoheren S&T Development Co., Ltd.
Cai Jialong
MD Registered Engineer
Floor 4, No 2 plant, No. 14, Zhongxing Road, Xiuxin
Community, Kengzi Street, Pingshan District
Shenzhen, Guangdong 518000
China

Re: K231749
Trade/Device Name: Radio Frequency System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 11, 2023
Received: June 15, 2023

Dear Cai Jialong:

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,

Mark Trumbore -S Digitally signed by Mark Trumbore -S
Date: 2023.10.19 15:32:33 -04'00'

Mark Trumbore, 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)*

Device Name
Radio Frequency System

Indications for Use *(Describe)*
The Radio Frequency 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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# 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

## 1. General Information


| | |
|---|---|
| Submitter: | Shenzhenshi Sincoheren S&T Development Co., Ltd.<br>Floor 4, No 2 plant, No. 14, Zhongxing Road, Xiuxin Community, Kengzi Street, Pingshan District, Shenzhen City, Guangdong Province, China |
| Contact Person: | Cai Jialong<br>MD Registered Engineer<br>Tel: +86-13424006986<br>Email:caijl@medsmt.com |
| Summary Preparation Date: | August 21, 2023 |


## 2. Device Name and Code

Trade/Common Name: Radio Frequency System

Classification Name: Electrosurgical, Cutting & Coagulation & Accessories

Classification: Class II

Product Code: GEI

Regulation Number: 21 CFR 878.4400

Review Panel: General & Plastic Surgery

## 3. Predicate Device

The INFINI Radiofrequency System (K121481).

This predicate device has not been subject to a design-related recall.

No reference devices were used in this submission.

## 4. Device Description

The Radio Frequency System consists of a host with an LCD touch screen control panel, moving base, treatment handle and pedal switch. The treatment handle includes a handpiece and a sterilized tip. And the sterilized tip is classified into two type, microneedle electrodes and RF electrodes. The treatment parameters are entered via the touchscreen control panel that also displays system output information during treatment. Microneedle electrodes come in light contact with the epidermis of

the patient and minimally penetrate the epidermis while RF electrodes not penetrate. RF POWER, ON TIME (RF POWER×ON TIME = RF Energy), DEPTH, are user-selectable via the control panel. The RF Power output is controlled to insure for a given time that a determinate RF Energy is delivered to the bipolar electrodes. The handpiece is held at right angles to the target tissue. As the RF energy passes into the skin, it generates an electro-thermal reaction capable of coagulating the tissue surrounding the uninsulated portion of the electrodes.

**5. Indications for Use**

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

**6. Technological Characteristics in Comparison to the Predicate Device**

The subject device has the same intended use and indications for use and the same fundamental scientific technology as the Predicate device, the INFINI Radiofrequency System cleared in K121481. The subject device design, technology, and the principles of operation are the same as the predicate device. The Radio Frequency System and the Predicate device are bipolar radio frequency systems, with delivery methods through microneedles inserted from the handpiece and the tip. The Radio Frequency System and the predicate device are minimally invasive radio frequency devices employing bipolar microneedle electrode system. The subject device has the same power, same treatment duration, needle diameter, and needle depth as the predicate device. Therefore, the minor differences do not raise any new safety and effectiveness questions because the parameters of the Subject device are similar to those of the predicate device.

**7. Substantial Equivalence Table**

| Description | Radio Frequency System | INFINI Radiofrequency System(K121481) | Comments |
|---|---|---|---|
| **Manufacturer** | Shenzhen Sincoheren S&T Development Co., Ltd. | Lutronic Corporation | |
| **Indication for Use** | The Radio Frequency System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. | The INFINI Radiofrequency System is intended for use in dermatologic and general surgical procedures for electrocoagulation and | Same as predicate |

| Description | Radio Frequency System | INFINI Radiofrequency System(K121481) | Comments |
|---|---|---|---|
| | | hemostasis, and the percutaneous treatment of facial wrinkles. | |
| **Prescription/Over-the Counter Use** | Prescription Use | Prescription Use | Same as predicate |
| **System Type** | Bipolar RF (Radio frequency) | Bipolar RF (Radiofrequency) | Same as predicate |
| **Frequency** | 1 MHz | 1 MHz | Same as predicate |
| **Max Output Power** | 50 W | 50 W | Same as predicate |
| **Operation Mode** | Fractional RF | Fractional RF | Same as predicate |
| **Treatment Duration(Time)** | 10~1000 ms | 10~1000 ms | Same as predicate |
| **Tips** | 49-pin: 7×7 microneedle electrodes, 10.5 mm×10.5 mm spot size, microneedle electrodes depth adjustment 0.5~3.5 mm<br>25-pin: 5×5 microneedles electrodes, 10.5 mm×10.5 mm spot size, microneedle electrodes depth adjustment 0.5~3.5 mm<br>49-RF: 7×7 RF electrodes, 10.5 mm×10.5 mm spot size, no electrodes depth adjustment | 49-pin:7×7 microneedles, 10×10 mm microneedle depth adjustment 0.5~3.5 mm spot size, microneedle depth adjustment 0.5~3.5 mm | Different. Additions of tip type in the subject device. |
| **Electrode Diameter** | Microneedle electrodes:2μm,<br>RF electrodes:600 μm | 200 μm | Different. Additions of tip type in the subject device. |
| **Output Control** | Foot/ Finger switch | Foot switch | Different. Additions of output control in the subject device. |
| **Electrode Material** | Gold plated stainless steel | Gold plated stainless steel | Same as predicate |

Shenzhen Sincoheren S&T Development Co., Ltd. has removed from the subject device the percutaneous treatment of facial wrinkles as an Indication for use. The subject device and the

predicate device have the same Indication for Use.
The following differences exist between the Subject Device and Predicate Device:
• The Subject Device use an additional type of tip(49-RF) and two models of microneedle electrodes(49-pin and 25-pin) but the Predicate Device only use one model of microneedle electrodes(25-pin).
• The finger switch is an addition to the Subject Device.

**8. Performance Date**

The following performance data were provided in support of the substantial equivalence determination:

**Biocompatibility testing**

The patient contacting component of the subject device is the tip and the biocompatibility tests were conducted in accordance with ISO 10993-1.
• In Vitro Cytotoxicity Test: ISO 10993-5: 2009
• Skin Sensitization Test: ISO 10993-10:2021
• Intracutaneous Reactivity Test: ISO 10993-23:2021
• Acute Systemic Toxicity Test: ISO 10993-11:2017
• Pyrogen Test: ISO 10993-11:2017

**Sterilization Validation**

Sterilization validation of the tip has been conducted per the standard ISO 10993-7:2008 for Ethylene Oxide(standard ISO 11135:2014).

**Shelf-life Validation**

The shelf-life validation of the device has been conducted using the accelerated aging method in accordance to ASTM F1980-16.

**Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety testing and EMC testing were conducted on the Radio frequency System complying with the IEC 60601-1 standard, the IEC 60601-1-6 standard for safety and the IEC 60601-1-2 standard for EMC.

**Software Verification and Validation Testing**

Software Verification and Validation Testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could indirectly result in minor injury to the patient or operator.

No preclinical and clinical data was provided in this submission.

**Conclusion**

The subject device shares a similar design and intended use to its predicate device(K121481). Additionally, principles of operation, performance characteristics, technological characteristics are similar between the subject device and its predicate devices. The results of verification and validation activities, i.e., testing to standards and performance testing of the devices, have demonstrated substantial equivalence of the subject device to its predicate devices. The minor differences in the subject device do not raise new types of questions regarding safety and efficacy, and the data presented in this 510(k) Premarket Notification supports the contention that the subject device is substantially equivalent to the predicate device.