DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 13, 2017

ILOODA Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
Houston, Texas 77025

Re: K170325
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
Dated: May 12, 2017
Received: May 15, 2017

Dear Mr. Kim:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170325

Device Name
SECRET RF
Micro-Needle Fractional RF

Indications for Use *(Describe)*

SECRET RF is intended for use in dermatologic and general surgical procedures for electro-coagulation 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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Special 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: 5/10/2017

I. SUBMITTER

Submitter's Name :	ILOODA CO LTD.
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Submitter's Telephone:	+82-31- 210-1622
Contact person:	Yun-Jung HA (yjha@ilooda.com) / RD Manager
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DEVICE	
Trade/proprietary name:	Secret ^{RF}
Common or Usual Name:	Micro-needle Fractional RF
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI, OUH)
Regulatory Class:	Class II
Prescription Use.	

PREDICATE DEVICE

Primary Device Manufacturer:	ILOODA CO.,LTD
Device Name:	FRAXIS DUO_RF PART
510(k) Number:	K160312
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI, OUH)
Regulatory Class:	Class II

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

II. DEVICE DESCRIPTION

Secret RF's High Frequency(=Radio Frequency) includes the system main body, a bipolar handpiece(Two type) with disposable micro-needle type electrodes, footswitch and an LCD touch screen control panel.

The HF energy is delivered to the target tissue using a handpiece and disposable tip(micro needle 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 thermal reaction, which is capable of coagulating the tissue. Using the micro needle tip, the Secret RF system creates heat within the target dermal tissue via micro-needles inserted from the tip.

III. INDICATIONS FOR USE:

Secret RF is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis

IV. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Proposed device	Predicate device	Remark
Model name	Secret RF	FRAXIS DUO (K160312)	SE
Manufacturer	ILOODA CO.,LTD	ILOODA CO.,LTD	
	Secret RF is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	**- CO2 LASER Part:** Fractional mode is indicated only for ablative skin resurfacing. Non-fractional mode is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues in medical specialties including aesthetic (dermatology and plastic surgery), Otorhinolaryngology (ENT), gynecology, neurosurgery, dental and oral surgery and genitourinary surgery. **-HF electrosurgical Part :** The FRAXIS DUO is also intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	SE
Electrosurgical RF applicator	MTR Applicator	Bipolar Applicator	SE
Output energy type	High frequency	High Frequency	SE
Delivery system	Bipolar Handpiece + Micro needle electrodes,	Bipolar Handpiece + Micro needle electrodes,	SE
Operation mode	Manual mode	Manual mode	SE
User interface	Color Touch Panel	Color Touch Screen	SE
Electrical Requirements	100-240VAC, 50/60Hz, 3-1A	100-240 VAC, 50-60Hz 5-3A,	SE
Dimensions (mm)	Main unit : 180(W)x460(D)x1100(H)	Main unit : 410(W)x601(D)x1071(H)	SE
Weight (Without arm)	40kg	45 kg	SE
Frequency	2MHz ± 10%	2MHz ± 10%	SE
Max power	Max 25W at 500Ω	Max 25W at 500Ω	SE
Total power delivered per treatment	Max.25W	Max.25W	SE
Power of per electrode pin	Max.25W	Max.25W	SE
Power density	Max 41W/㎠	Max 41W/㎠	SE
Current density	Max 0.3A/㎠	Max 0.3A/㎠	SE
RF duration	50 ms ~ 950 ms	50 ms ~ 950 ms	SE

	Proposed device	Predicate device	Remark
Treatment time	10~15min (recommended)	10~15min (recommended)	SE
Needle insert depth	0.5 ~ 3.5mm (0.1 step)	0.5 ~ 3.5mm (0.1 step)	SE
Intensity	0 ~ 10 LEVEL (2/5/10 STEP)	0 ~ 10 LEVEL (2/5/10 STEP)	SE
Repetition	0.2 / 0.5 / 1 / 2 sec / Single	0.2 / 0.5 / 1 / 2 sec / Single	SE
Connected handpiece	Bipolar handpieces	Bipolar handpieces	SE
Connected electrodes	MTR-AC-25 MTR-AC-64	MTR-AC-25 MTR-AC-64	SE

V. PERFORMANCE DATA

Configuration values indicating intensity and RF time for different areas of body are the same for the subject and the predicate device. The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility testing:

The patient contact components and materials are tested and validated according to ISO10993-1;2009. They are identical to the predicate device.

Non Clinical testing:

IEC 60601-1 Test for Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance. The requirements of specified standards were fulfilled.

IEC 60601-1-2 Test for Medical Electrical Equipment was performed for General Requirements for basic safety and essential performance (collateral standards: electromagnetic compatibility.

IEC 60601-2-2: 2009 Medical electrical equipment

Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

The requirements of specified standards were fulfilled.

Animal testing :

In vivo animal testing using micropig models was also conducted to obtain histological data of values for depth and zone of ablation and thermal damage immediately post treatment; 7 days post treatment; and 14 days post treatment.

The treatment was performed at the intensity(power) low, mid, high and depth of micro-needling 1.0mm, 2.0mm, 3.0mm.

VI. CONCLUSIONS

There are no significant differences in HF electrosurgical application between Secret ^{RF} and FRAXIS DUO, the predicate device. The proposed device does not raise any questions regarding safety and effectiveness. Secret ^{RF} has the same indication of use as the predicate devices and it shares the same technological characteristics as the predicate devices.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, it is the opinion of Ilooda Co, Ltd. that Secret ^{RF} is substantially equivalent in comparison with FRAXIS DUO, the predicate devices as described herein.