September 6, 2019

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

Re: K182355
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
Dated: July 29, 2019
Received: August 8, 2019

Dear Dave 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. 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)*
K182355

Device Name
Secret RF Smartcure Applicator

Indications for Use *(Describe)*

Secret RF Smartcure applicator 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.

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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: 7/29/2019

I. SUBMITTER

Submitter's Name :	ILOODA CO LTD.
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II. DEVICE NAME

Trade/proprietary name:	Secret ^{RF} Smartcure Applicator
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.	

III. PREDICATE DEVICE

Trade/proprietary name:	Secret ^{RF}
Common or Usual Name:	Micro-needle Fractional RF
510K number:	K170325
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI, OUH)

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Regulatory Class:	Class II
Prescription Use.	

IV. REFERENCE DEVICE 1

Trade/proprietary name:	AGNES
Common or Usual Name:	RF Electrosurgical device
510K number:	K160469
Regulation Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: GEI)
	21 CFR 878.5350 (Produce Code:KCW)
Regulatory Class:	Class II

V. REFERENCE DEVICE 2

Trade/proprietary name:	EVRF
510K number:	K112334
Common or Usual Name:	Electrosurgical, cutting & coagulation device & accessories
Regulation Number:	21 CFR 878.4400 (Product Code: ONQ)
Regulatory Class:	Class II

VI. DEVICE DESCRIPTION

Secret RF's High Frequency(=Radio Frequency) includes the system main body, a handpices with single-use 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.

The Secret RF is consists of ;

1) Secret RF main unit (FDA cleared K170325)
2) Bipolar type handpieces with Bipolar type micro-needle electrodes (FDA cleared K170325)
3) Secret ^{RF} Smartcure applicator

The Secret RF Smartcure Applicator consists of :

- Smartcure handpiece
- Monopolar type micro-needle electrodes

(MTR-AC-01 , MTR-AC-04, MTR-AC-27G, K3i)

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VII. INDICATIONS FOR USE

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

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Secret RF's Smartcure applicator changes the treatment(operation) mode depending on the electrode to be connected.

Since the specifications for each operation mode are different, we provide an equivalent comparison table for each mode.

Table 1. Technical Comparison for the SC mode

	Proposed device	Predicate Device	
Model name	Secret RF Smartcure Applicator (Model: MTR-AC-01 , MTR-AC-04, MTR-AC-27G	Secret RF	
Manufacturer	ILOODA CO.,LTD	ILOODA CO.,LTD	
510(k)number	K182355	K170325	
Intended use	Secret RF Smartcure Applicator is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	Secret RF is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	Same
Main unit	Secret RF	Secret RF	
Connected handpiece	Monopolar	Bipolar handpiece	Reference device #1
Output energy type	High frequency	High frequency	Same
Electrode type	Monopolar micro needle	Bipolar micro needle	Reference device #2
Frequency	2MHz ± 10%	2MHz ± 10%	Same
Max power	Max 45W at 500Ω	Max 25W at 500Ω	Different
RF duration (ON/OFF RF TIME)	Continuous, 100 ms ~ 3000 ms	50 ms ~ 950 ms	Different
Treatment time	10~15min (recommended)	10~15min (recommended)	Same

	Proposed device	Reference device 1	Remark
Model name	Secret RF Smartcure Applicator (Model: MTR-AC-01 , MTR-AC-04, MTR-AC-27G	AGENS	
Manufacturer	ILOODA CO.,LTD	Gowoonsesang Cosmetics Co., Ltd.	
510(k)number	K182355	K160469	

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		Proposed device	Reference device 1	Remark
Intended use		Secret RF SmartcureApplicator is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	AGNES is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	Same
Main unit		Secret RF	AGENS	
Connected handpiece		Monopolar handpiece	Monopolar handpiece	Same
Output energy type		High frequency	High frequency	Same
Electrode type		Monopolar micro needle type	Monopolar micro needle type	Same
Frequency		2MHz ± 10%	1MHz	
Max power		Max 45W at 500Ω	Max 46 W at 200 Ω	
RF duration (ON/OFF RF TIME)		Continuous, 100 ms ~ 3000 ms	50ms ~ 2000ms	
Treatment time		10~15min (recommended)	Unknown	
Connected electrods	Needle Length	0.8/1.25/1.5/ 2.0 mm	0.8/1.25/1.5/ 2.0 mm	Same
	Thickness	0.2mm	0.2mm	Same
	Materials	Stainless steel 304, Insulating Coating: Teflon PTFE	Stainless steel 304, Insulating Coating: Teflon PTFE	Same
Single Use		Single Use	Single Use	Same
Sterilization		EO gas	EO gas	Same

Table 2. Technical Comparison for the VC mode

	Proposed device	Reference device 2	Remark
Model name	Secret RF Smartcure Applicator (Model K3i)	EVRF	
Manufacturer	ILOODA CO.,LTD	F Care System NV	
510(k)number	K182355	K130283	
Intended use	Secret RF Smartcure Applicator is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.	The EVRF System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.	Same
Output energy type	High frequency	High frequency	Same
Main unit	Secret RF	EVRF	Same
Electrode type	Monopolar	Monopolar	Same
Frequency	4MHz ± 10%	4MHz ± 10%	Same
Max power	Max 18W at 500Ω	Max 25W at 500Ω	
RF duration (ON/OFF RF TIME)	10ms~900ms	50 ms ~ 950 ms	
Treatment time	10~15min	10~15min	Same

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	Proposed device	Reference device 2	Remark
	(recommended)	(recommended)	
Connected electrodes	Cleared FDA (Recommended K883892)	Needles are purchased from Ballet Technologies, Ltd (K883892)	

IX. PERFORMANCE DATA

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.

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.

X. CONCLUSIONS

Secret ^{RF} Smartcure applicator with electrode device has the same intended use and similar indications as its predicate devices. The technology of the predicate devices is also the same.

The envelope of power and frequency of the submitted Secret ^{RF} Smartcure applicator with electrodes are covered by the envelopes of its predicate devices.

Any minor differences in the human interface and accessories design do not raise any new types of safety and effectiveness issues, as verified by performance testing.

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In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Ilooda Co, Ltd. concludes that SECRET RF Smart Applicator is substantially equivalent in comparison SECRET RF (K170325), the predicate device, while it is similar to AGENS and EVRF, the reference devices, as described herein.