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.


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

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
Indications for Use

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.
Submitter’s HQ Address: 120, Jangan-ro 458 Beon-gil, Jangan-Gu, Suwon-Si Gyeonggido, KOREA, 16200
Submitter’s Telephone: +82-31-210-1622
Contact person: Yun-Jung HA (yjha@ilooda.com) / RD Manager

Official Correspondent: Dave Kim (davekim@mtech-inc.net)
Address: 8310 Buffalo Speedway, Houston, TX 77025
Telephone: +713-467-2607
Fax: +713-583-8988

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)
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 (Product 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 handpieces 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)
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 |

<table>
<thead>
<tr>
<th>Proposed device</th>
<th>Reference device 1</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model name</td>
<td>Secret RF</td>
<td>AGENS</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>ILOODA CO., LTD</td>
<td>Gowoonsesang Cosmetics Co., Ltd.</td>
</tr>
<tr>
<td>510(k)number</td>
<td>K182355</td>
<td>K160469</td>
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</table>
### Table 2. Technical Comparison for the VC mode

<table>
<thead>
<tr>
<th></th>
<th>Proposed device</th>
<th>Reference device 1</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended use</strong></td>
<td>Secret RF Smartcure Applicator is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.</td>
<td>AGNES is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Main unit</strong></td>
<td>Secret RF</td>
<td>AGENS</td>
<td></td>
</tr>
<tr>
<td><strong>Connected handpiece</strong></td>
<td>Monopolar handpiece</td>
<td>Monopolar handpiece</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Output energy type</strong></td>
<td>High frequency</td>
<td>High frequency</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Electrode type</strong></td>
<td>Monopolar micro needle type</td>
<td>Monopolar micro needle type</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>2MHz ± 10%</td>
<td>1MHz</td>
<td></td>
</tr>
<tr>
<td><strong>Max power</strong></td>
<td>Max 45W at 500Ω</td>
<td>Max 46W at 200Ω</td>
<td></td>
</tr>
<tr>
<td><strong>RF duration (ON/OFF RF TIME)</strong></td>
<td>Continuous, 100 ms ~ 3000 ms</td>
<td>50ms ~ 2000ms</td>
<td></td>
</tr>
<tr>
<td><strong>Treatment time</strong></td>
<td>10~15min (recommended)</td>
<td>Unknown</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Needle Length</strong></td>
<td>0.8/1.25/1.5/ 2.0 mm</td>
<td>0.8/1.25/1.5/ 2.0 mm</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Thicknes</strong></td>
<td>0.2mm</td>
<td>0.2mm</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td>Stainless steel 304, Insulating Coating: Teflon PTFE</td>
<td>Stainless steel 304, Insulating Coating: Teflon PTFE</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Single Use</strong></td>
<td>Single Use</td>
<td>Single Use</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Sterilization</strong></td>
<td>EO gas</td>
<td>EO gas</td>
<td>Same</td>
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<table>
<thead>
<tr>
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<th>Proposed device</th>
<th>Reference device 2</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model name</strong></td>
<td>Secret RF Smartcure Applicator (Model K3i)</td>
<td>EVRF</td>
<td></td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
<td>ILOODA CO.,LTD</td>
<td>F Care System NV</td>
<td></td>
</tr>
<tr>
<td><strong>510(k)number</strong></td>
<td>K182355</td>
<td>K130283</td>
<td></td>
</tr>
<tr>
<td><strong>Intended use</strong></td>
<td>Secret RF Smartcure Applicator is intended for use in dermatologic and general surgical procedures for electro-coagulation and hemostasis.</td>
<td>The EVRF System is intended for the epilation and for the treatment of lower limb spider vein or telangiectasia by thermocoagulation.</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Output energy type</strong></td>
<td>High frequency</td>
<td>High frequency</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Main unit</strong></td>
<td>Secret RF</td>
<td>EVRF</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Electrode type</strong></td>
<td>Monopolar</td>
<td>Monopolar</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>4MHz ± 10%</td>
<td>4MHz ± 10%</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Max power</strong></td>
<td>Max 18W at 500Ω</td>
<td>Max 25W at 500Ω</td>
<td></td>
</tr>
<tr>
<td><strong>RF duration (ON/OFF RF TIME)</strong></td>
<td>10ms~900ms</td>
<td>50 ms ~ 950 ms</td>
<td></td>
</tr>
<tr>
<td><strong>Treatment time</strong></td>
<td>10~15min</td>
<td>10~15min</td>
<td>Same</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Proposed device</th>
<th>Reference device 2</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>(recommended)</td>
<td>(recommended)</td>
<td></td>
</tr>
<tr>
<td>Connected electrodes Cleared FDA (Recommended K883892)</td>
<td>Needles are purchased from Ballet Technologies, Ltd (K883892)</td>
<td></td>
</tr>
</tbody>
</table>

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.
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.