September 11, 2018

Medical Device Branch of Zhangzhou Easepal Industrial Co., Lt
% Iris Fung
PM
SGS-CSTC Standards Technical Services Co., Ltd.
108 Kezhu Road
Scienteck Park Guangzhou Economic & Technology Dept
Guangzhou, CN

Re: K181568
  Trade/Device Name: IPL Salon Hair Reduction System
  Regulation Number: 21 CFR 878.4810
  Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
  Regulatory Class: Class II
  Product Code: OHT
  Dated: June 10, 2018
  Received: June 14, 2018

Dear Iris Fung:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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
Indications for Use

The IPL Salon Hair Reduction System (Model: F60001) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen.

Type of Use (Select one or both, as applicable)

- [ ] Prescription Use (Part 21 CFR 801 Subpart D)
- [x] Over-The-Counter Use (21 CFR 801 Subpart C)

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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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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510(k) Summary

Date of the summary prepared: September 8, 2018

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter’s Information

Applicant

- Company Name: Medical Device Branch of Zhangzhou Easepal Industrial Co., Ltd.
- Address: 4th Floor of Building #1, No.228, Jiaosong Road, Taiwanese Investment Zone, Zhangzhou, Fujian, China.
- Phone: +86 1366 609 7743
- Fax: +86 059 6626 8816
- Contact Person (including title): Bruce Wu
- E-mail: brucewu@easepal.com.cn

Application Correspondent:

- SGS-CSTC Standards Technical Services Co., Ltd.
- Address: 198 KEZHU Road, SCIENTECH Park Guangzhou Economic & Technology Development District, Guangzhou, Guangdong, CHINA
- Contact Person: Ms. Iris Fung
- Tel: +86-20-32136908
- Email: Iris.Fung@sgs.com

2. Subject Device Information

- Trade Name: IPL Salon Hair Reduction System
- Common Name: IPL Salon Hair Reduction System
- Classification name: Light Based Over-The-Counter Hair Removal
- Review Panel: General & Plastic Surgery
- Product Code: OHT
- Regulation Class: 2
- Regulation Number: 878.4810
3. Predicate Device Information

<table>
<thead>
<tr>
<th>Predicate Type</th>
<th>Primary Predicate Device</th>
<th>Reference Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) Number</td>
<td>K161428</td>
<td>K140631</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>878.4810</td>
<td>878.4810</td>
</tr>
<tr>
<td>Product Code</td>
<td>OHT</td>
<td>ONF</td>
</tr>
<tr>
<td>Device Name</td>
<td>PerfectSmooth</td>
<td>Lumena FH Hair Removal System</td>
</tr>
<tr>
<td>Sponsor</td>
<td>Shen Zhen CosBeauty Co., Ltd.</td>
<td>Shaser, Inc.</td>
</tr>
</tbody>
</table>

2. Device Description

IPL Salon Hair Reduction System, Model: F60001, a small over-the-counter device, is a home-use device for the permanent reduction of hair growth based on Intense Pulsed Light (IPL). Emission activation is by finger switch. Device includes a treatment window head, a facial adaptor and battery charger/AC cord. It is used AC Powered(100-240 V AC; 50/60 Hz). The weight of the device is 650g, and the size is 143 x 69.5 x 43mm (H*W*D). The device incorporates Intense Pulse Light (IPL) technology. The purpose of the light is to heat the root where the hair grows.

5. Intended Use / Indications for Use

The IPL Salon Hair Reduction System (Model: F60001) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

6. Design

A flash of Intense Pulsed Light (IPL) is directed at the skin and the light energy travels along the pigment in the hair, where it is converted to heat energy. It is the heat energy that disables the hair follicle preventing the hair from regrowing. Treated hairs will shed naturally within a couple of weeks of treatment and will not regrow. Each treatment will only be effective on hairs that are in their active growth phase at the time, so it is important to follow a course of treatments over a twelve-week period to ensure all hairs are treated.

The device contains a Xenon Lamp and a skin proximity sensor to detect appropriate skin contact. If the IPL Hair Removal Device is not properly applied to the treatment area (in full contact with the skin), the device cannot be triggered. The device is designed for use on the legs, underarms, bikini line, chest, stomach, back, arms and on the face below the cheekbones [although not recommended for use on male facial hair].

7. Materials

Listed below is the material that comes in contact with the user.

<table>
<thead>
<tr>
<th>Component of</th>
<th>Material of</th>
<th>Body Contact</th>
<th>Contact Duration</th>
</tr>
</thead>
</table>
Relevant biocompatibility evaluations were performed and tests reports are provided to claim substantial equivalence.

8. Physical characteristics

<table>
<thead>
<tr>
<th>Basic Unit Characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance* with 21 CFR 898</td>
<td>N/A</td>
</tr>
<tr>
<td>Main Unit Weight</td>
<td>650g</td>
</tr>
<tr>
<td>Main Unit Dimension</td>
<td>143<em>69.5</em>43mm(H<em>W</em>D)</td>
</tr>
<tr>
<td>Housing Materials of main unit</td>
<td>PC2805</td>
</tr>
<tr>
<td>Indicator</td>
<td>Indicates power information, intensity level information.</td>
</tr>
<tr>
<td>Environment for operation</td>
<td>Temperature: 10°C~35°C</td>
</tr>
<tr>
<td></td>
<td>Humidity: 3%~75%</td>
</tr>
<tr>
<td></td>
<td>Pressure: 700~1060hPa</td>
</tr>
<tr>
<td>Storage and Transport Conditions</td>
<td>Temperature: -35°C~70°C</td>
</tr>
<tr>
<td></td>
<td>Humidity: 10%~90%</td>
</tr>
<tr>
<td></td>
<td>Pressure: 500~1060hPa</td>
</tr>
<tr>
<td>Compliance with Voluntary Standards</td>
<td>Yes, Comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57</td>
</tr>
<tr>
<td>Patient leakage current</td>
<td>Comply with IEC 60601-1</td>
</tr>
<tr>
<td>Power Source</td>
<td>Supplied by external adapter</td>
</tr>
<tr>
<td>Software/Firmware/Microprocessor Control?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Output Intensity Level</td>
<td>5</td>
</tr>
<tr>
<td>Output energy with facial adaptor</td>
<td>Level 1: 8.62J</td>
</tr>
<tr>
<td></td>
<td>Level 2: 9.45J</td>
</tr>
<tr>
<td></td>
<td>Level 3: 10.64J</td>
</tr>
<tr>
<td></td>
<td>Level 4: 11.48J</td>
</tr>
<tr>
<td></td>
<td>Level 5: 12.70J</td>
</tr>
<tr>
<td>Emitted Light Spectrum</td>
<td>475nm~1200nm Max</td>
</tr>
<tr>
<td>Max Energy density:</td>
<td>Up to 5 J/cm²</td>
</tr>
<tr>
<td>Treatment Area (regular window)</td>
<td>3.025 [cm³]</td>
</tr>
<tr>
<td>Treatment area (facial adapter)</td>
<td>1.72 [cm³]</td>
</tr>
<tr>
<td>Max number of Flashes:</td>
<td>150,000 times</td>
</tr>
<tr>
<td>Non-continuous operation</td>
<td>1min on / 3min off</td>
</tr>
</tbody>
</table>
10. Test Summary of non-clinical test
IPL Salon Hair Reduction System, Model: F60001 has been evaluated for the safety and performance by lab bench testing as follow:
• Electrical safety test according to IEC 60601-1 and IEC 60601-2-57 standards
• Electromagnetic compatibility test according to IEC 60601-1-2 standard
• Software verification and validation test according to the requirements of the FDA “Guidance for PreMarket Submissions and for Software Contained in Medical Devices”
• Biocompatibility test according to ISO10993-5 and ISO10993-10.
• Usability study testing shown that the device can be used as intended.

11. Summary of the Technological Similarities and Differences
The technological characteristics, features, specifications, materials, and intended use of IPL Salon Hair Reduction System, Model: F60001 is substantially equivalent to the predicate devices quoted above.
The differences between the subject device and predicate devices do not raise different question of safety or effectiveness.

<table>
<thead>
<tr>
<th>Elements of Comparison</th>
<th>Subject Device</th>
<th>Primary Predicate Device</th>
<th>Reference Predicate Device</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name and Model</td>
<td>IPL Salon Hair Reduction System, Model: F60001</td>
<td>PerfectSmooth (CB-014)</td>
<td>Lumena FH Hair Removal System</td>
<td>--</td>
</tr>
<tr>
<td>510(k) Number</td>
<td>Applying</td>
<td>K161428</td>
<td>K140631</td>
<td>--</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Medical Device Branch of Zhangzhou Easepal Industrial Co.,Ltd.</td>
<td>Shen Zhen CosBeauty Co., Ltd.</td>
<td>Shaser, Inc.</td>
<td>--</td>
</tr>
<tr>
<td>Intended Use</td>
<td>The IPL Salon Hair Reduction System (Model: F60001) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. It is also intended for permanent reduction in unwanted hair.</td>
<td>The IPL Hair Removal Device Joy Version is an over-the-counter device intended for removal of unwanted hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas</td>
<td>Lumena FH is an over the Counter device intended to provide phototherapeutic light to the body. It is also intended for removal of unwanted hair by using a selective photothermal treatment. It is also indicated for the</td>
<td>SE</td>
</tr>
</tbody>
</table>

## Power Supply

<table>
<thead>
<tr>
<th>Power Supply</th>
<th>100-240 VAC, 50/60Hz</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Technology</th>
<th>IPL</th>
</tr>
</thead>
</table>
Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen. Such areas as legs.

- **Source Energy**
  - Supplied by external adapter
  - an external power supply
  - AC Mains
  - SE

- **‘Use’ Classification**
  - OTC
  - OTC
  - OTC
  - SE

- **Device Classification**
  - Class II
  - Class II
  - Class II
  - SE

- **Device Type**
  - Intense Pulsed Light
  - Intense Pulsed Light
  - Intense Pulsed Light
  - SE

- **Wavelength (nm)**
  - 475nm~1200nm
  - 475nm~1200nm
  - 400nm~1200nm
  - SE

- **Max. Fluence (J/cm²)**
  - Max 5.0 [Joules/cm²]
  - 4.7[Joules/cm²]
  - Max 10 [Joules/cm²]
  - SE

- **Spot Size (cm²)**
  - 1.72 cm² or 3.02 cm²
  - 4.5[cm²]
  - 2[cm²]
  - SE

- **Pulse duration**
  - 11-12 ms
  - 11-13 milliseconds
  - --
  - SE

- **Energy medium**
  - Xenon Arc Flashlamp
  - Xenon Arc Flashlamp
  - Xenon Arc Flashlamp
  - SE

- **Pulsing Control**
  - Finger switch
  - Finger switch
  - Finger switch
  - SE

- **Number of Output Channels**
  - One channel
  - One channel
  - One channel
  - SE

- **Output Intensity Level**
  - 5 levels
  - --
  - 5 levels
  - SE
### Elements of Comparison

<table>
<thead>
<tr>
<th>Elements of Comparison</th>
<th>Subject Device</th>
<th>Primary Predicate Device</th>
<th>Reference Predicate Device</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software/Firmware/Microprocessor Control?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>SE</td>
</tr>
<tr>
<td>60601 Compliance with Voluntary Standards</td>
<td>Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57</td>
<td>Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57</td>
<td>Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57</td>
<td>SE</td>
</tr>
<tr>
<td>Compliance* with 21 CFR 898</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>SE</td>
</tr>
<tr>
<td>Weight</td>
<td>650g</td>
<td>--</td>
<td>1Kg</td>
<td>Note 1</td>
</tr>
<tr>
<td>Dimensions</td>
<td>143<em>69.5</em>43mm (H<em>W</em>D)</td>
<td>--</td>
<td>22<em>16</em>78cm (H<em>W</em>D)</td>
<td>Note 1</td>
</tr>
</tbody>
</table>

### Standards

<table>
<thead>
<tr>
<th>Standards</th>
<th>Subject Device</th>
<th>Primary Predicate Device</th>
<th>Reference Predicate Device</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biocompatibility</td>
<td>All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.</td>
<td>All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.</td>
<td>All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.</td>
<td>SE</td>
</tr>
<tr>
<td>Electrical Safety</td>
<td>Comply with IEC60601-1 and IEC60601-2-57</td>
<td>Comply with IEC 60601-1 and IEC 60601-2-57</td>
<td>Comply with IEC 60601-1 and IEC 60601-2-57</td>
<td>SE</td>
</tr>
</tbody>
</table>

### Comparison in Detail(s):

**Note 1:**
“Power Source(s)”, “Weight”, “Dimensions” is belong to basic characteristics. Although it is a little different from the predicate devices, it will not affect the main function and the intended use of the device. They all also comply with IEC 60601-1 requirements. So the differences will not raise any safety or effectiveness issue.

**Note 2:**
Although the Max. Fluence of subject device is a little larger than the one of the Primary Predicate device, but comparing to Reference Predicate device, the energy density of subject device is less than 10 Joules/cm². And they all comply with IEC 60601-1, IEC 60601-2-57 requirement. So the differences of function specification will not raise any safety or effectiveness issue.

**Note 3:**
Although the wavelength of subject device is a little different from the predicate devices, but they all comply with IEC 60601-1, IEC 60601-2-57 requirement. And the wavelength of subject device is in the range of the one of predicted device “PerfectSmooth”. So the differences of function specification will not raise any safety or effectiveness issue.

**Note 4:**
The types of “Spot Size (cm2)” of subject device, and there is minor difference between the subject device and the predicate devices. And they all comply with IEC 60601-1, IEC60601-2-57 requirement. So the differences of Spot size will not raise any safety or effectiveness issue.

**Clinical testing:**
No clinical testing was performed

**Conclusion:**

The subject device “IPL Salon Hair Reduction System, Model: F60001” is substantial Equivalence to all predicate devices.