DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 1, 2016

Stetic Medical Aesthetics Development (Shenzhen) Co., Ltd.
% Iris Fung
Official Correspondent
SGS-CSTC Standards Technical Services Co., Ltd.
198 Kezhu Road, Scientech Park Guangzhou
Guangzhou, CN

Re: K161565
Trade/Device Name: Duo
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: ONF, OHT
Dated: May 30, 2016
Received: June 6, 2016

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. 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 Part 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 , 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 yours,

Christopher J. Ronk -S

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)*
K161565

Device Name
DUO, Model: IPL-HH380-IT

Indications for Use *(Describe)*
The DUO (Model: IPL-HH380-IT) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. The DUO 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 regrowing 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) ☒ 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 the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor

- Company Name: STETIC MEDICAL AESTHETICS DEVELOPMENT (SHENZHEN) CO. ,LTD
  - Address: 10-11th Floor, Bensi Building, New High-Tech-Park, Ganli Village, Buji District, Shenzhen, China
- Phone: 86-755 6121 8197
- Fax: 86-755 2598 1606
- Contact Person (including title): Yejuan
- E-mail: info@steticsensebeauty.com

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: DUO, Model: IPL-HH380-IT
- Common Name: DUO
- Classification name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
- Review Panel: General & Plastic Surgery
- Product Code: ONF
- Regulation Class: 2
- Regulation Number: 878.4810

3. Predicate Device Information

Sponsor	Shaser, Inc.	EL Global Trade Ltd.
Device Name	Lumena FH Hair Removal System	Sensi Light Mini
510(k) Number	K140631	K140527
Product Code	ONF	OHT
Regulation Number	878.4810	878.4810
Regulation Class	2	2

4. Device Description

DUO, Model: IPL-HH380-IT,a small over-the-counter,is a home-use device for the permanent reduction of hair growth based on Intense Pulsed Light (IPL). It works below the skin's surface and does not involve

any cutting or pulling, reducing hair growth with minimal pain.A personal Light-Based Hair Removal System.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 280g, and the size is 130 x 70 x 30 mm (H x W x D).The device incorporates Intense Pulse Light (IPL) technology. The purpose of the light is to heat the root where the hair grows.The device contains a Quartz Xenon Lamp,a skin proximity sensor and a skin pigmentation sensor to detect appropriate skin tones. If the DUO is not properly applied (in full contact with the skin) or user skin tone is too dark/tanned, the DUO will not trigger a pulse. The spot size (treatment area) in the DUO device is 3 cm^2.When the lamp had been subjected to operation of 300000 cycles, then the indicator light on the device is flashing at the frequency of 2Hz , it means that the device life has reached the end, the device stops working.

5. Intended Use / Indications for Use

The DUO (Model: IPL-HH380-IT) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. The DUO 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 regrowing when measured at 6. 9. and 12 months after the completion of a treatment regimen.

6. Design

DUO, Model: IPL-HH380-IT,a small over-the-counter,is a home-use device for the permanent reduction of hair growth based on Intense Pulsed Light (IPL). It works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain.A personal Light-Based Hair Removal System.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 280g, and the size is 130 x 70 x 30 mm (H x W x D).The device incorporates Intense Pulse Light (IPL) technology. The purpose of the light is to heat the root where the hair grows. The device contains a Quartz Xenon Lamp, a skin proximity sensor and a skin pigmentation sensor to detect appropriate skin tones. If the DUO is not properly applied (in full contact with the skin) or user skin tone is too dark/tanned, the DUO will not trigger a pulse. The spot size (treatment area) in the DUO device is 3 cm^2.When the lamp had been subjected to operation of 300000 cycles, then the indicator light on the device is flashing at the frequency of 2Hz , it means that the device life has reached the end, the device stops working.

7. Materials

There are two user directly contracting components in the subject device as the following list.

Component of Device Requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Housing	PC 2805	Surface-contacting device: skin	Maximum 30 minutes(< 24hours)
Output contacts	PC 2805	Surface-contacting device: skin	Maximum 30 minutes(< 24hours)

The Nature of body contact is surface, skin contact. And the contact duration is less than 24 hours. According to Table 1 - Initial evaluation tests for consideration in ISO 10993-1, the applicable biological effect is:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity

1. Cytotoxicity Test

(1) Test Method

MTT Method in ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, Edition 3.0, 2009;

(2) Passing Criteria

As our subject device is only for limited skin contacting, we set the criteria for NON-TOXIC to be “no more than Grade 2” according to United States Pharmacopoeia.

(3) Test Result

The Cytotoxicity test result showed the device had no toxicity to L929 cell. The test result is passed the criteria.

2. Skin Sensitization Test

(1) Test Method

Guinea Pig Maximization Test in ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization, Edition 3.0, 2010;

(2) Passing Criteria

As our subject device is for limited skin contacting, we set the criteria to be “Grade 0” according to United States Pharmacopoeia.

(3) Test Result

The Skin Sensitization test result for device is Grade 0. The test result is passed the criteria.

3. Skin Irritation Test

(1) Test Method

0.9% Sodium Chlorid Injection and Sesame oil Extract in ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization, Edition 3.0, 2010;

(2) Passing Criteria

As our subject device is for limited skin contacting, we set the criteria to be “0-0.4 for Irritation Index” according to United States Pharmacopoeia.

(3) Test Result

The Skin Irritation test results for Component is 0 for Irritation Index. The test result is passed the criteria.

8. Physical characteristics

Basic Unit Characteristics	
Compliance* with 21 CFR 898	No
Main Unit Weight	280g
Main Unit Dimension	130*70*30mm
Housing Materials of main unit	PC2805
Indicator	Indicates power information, LED of mode information, intensity level information.
Time Range (minutes)	30 mins
Environment for operation	Temperature: 10°C~35°C Humidity: 30~75%
Storage and Transport Conditions	Temperature: -15°C~55°C Humidity: 10~90%
Compliance with Voluntary Standards	Yes,Comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57
Patient leakage current	Comply with IEC 60601-1
Power Source	Supplied by external adapter
Software/Firmware/Microprocessor	Yes

Control?	
Specification	
Output Intensity Level	5
Output energy without facial adaptor	Level 1:>7.7J Level 2:>8.5J Level 3:>9.4J Level 4:>10.5J Level 5:>12J
Output energy with facial adaptor	Level 1:>4.0J Level 2:>4.7J Level 3:>5.4J Level 4:>5.9J Level 5:>6.7J
Emitted Light Spectrum	480nm~1200nm Max
Pulse Duration:	[<20ms]
Single pulse irradiation time	500ms
Emitted Energy Flue	5 [Joules/cm²]
Treatment Area (regular window)	3 [cm²]
Max pulses in lamp	up to 300,000
Power Supply	100-240 VAC, 50/60Hz
Technology	IPL

10. Test Summary

DUO, Model: IPL-HH380-IT has been evaluated the safety and performance by lab bench testing as following:

- 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”

11. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of DUO, model: IPL-HH380-IT is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**		**Remark**
Device Name and Model	DUO, Model: IPL-HH380-IT	Lumena FH Hair Removal System	Sensi Light Mini	--
510(k) Number	Applying	K140631	K140527	--

Manufacturer	STETIC MEDICAL AESTHETICS DEVELOPMENT (SHENZHEN) CO. ,LTD	Shaser, Inc.	EL Global Trade Ltd.	--
Intended Use	The DUO (Model: IPL-HH380-IT) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. The DUO 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 regrowing when measured at 6. 9. and 12 months after the completion of a treatment regimen.	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 removal of unwanted body and/or fhcial hair in adults with Fitzpatrick skin types I - IV. The Lumena PH 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 regrowing when measured at 6,9 and 12 months after the completion of a treatment regimen.	The sensi Light Mini is an over the counter devices intended for the removal of unwanted hair. The sensi Light Mini is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of treatment regimen.	SE
Source Energy	Supplied by external adapter	AC Mains	an external power supply	SE Note 1
'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)	480nm~1200nm	400nm~1200nm	475nm~1200nm	SE Note 2

Elements of Comparison	**Subject Device**	**Predicate Device**		**Remark**
Max. Fluence (J/cm2)	5 [Joules/cm²]	6 [Joules/cm²]	5 [Joules/cm²]	SE Note 2
Spot Size (cm2)	3 [cm²]	2[cm²]	3 [cm²]	SE Note 2
User Interface	LED Indicator lights	LED Indicator lights	LED Indicator lights	SE
Pulsing Control	Finger switch	Finger switch	Finger switch	SE
Control Mechanism	Microprocessor-based Control	Microprocessor-based Control	Microprocessor-based Control	SE
Number of Output Channels	One channel	One channel	One channel	SE

Output Intensity Level	5 levels	5 levels	--	SE
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	SE
60601Compliance with Voluntary Standards	Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57	Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57,	Yes Comply with IEC 60601-1 and IEC 60601-1-2,IEC60601-2-57,IEC60601-1-11	SE
Compliance* with 21 CFR 898	No	No	No	SE
Weight	280g	1Kg	--	SE Note 1
Dimensions	130*70*30mm	22*16*78cm (H*W*D)	--	SE Note 1
Standards				
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
Electrical Safety	Comply with	Comply with	Comply with	SE

Elements of Comparison	Subject Device	Predicate Device		Remark
	IEC60601-1 and IEC60601-2-57	IEC 60601-1 and IEC 60601-2-57	IEC 60601-1 and IEC 60601-2-57	

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 "Wavelength (nm)", "Max. Fluence (J/cm2)", and "Spot Size (cm2)" of subject device are a little different from the predicate devices, they all comply with IEC 60601-1,IEC60601-2-57,requirement.So the differences of function specification will not raise any safety or effectiveness issue.