October 2, 2019

Kam Yuen Plastic Products Ltd
% Jet Li
Regulation Manager
Guangzhou KEDA Biological Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, Cn

Re: K190820
Trade/Device Name: Aimanfun Lumea Comfort
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
Dated: March 24, 2019
Received: April 1, 2019

Dear Jet Li:

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,

Purva Pandya
Acting 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)*
K190820

Device Name
The Aimanfun Lumea Comfort (Model: A-2788)

Indications for Use *(Describe)*
The Aimanfun Lumea Comfort (Model: A-2788) is indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician, after training by a healthcare professional. The Aimanfun Lumea Comfort 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.

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K190820
510(k) Summary

Date of the summary prepared: October 2, 2019

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: Kam Yuen Plastic Products Ltd
- Address: No. 2, Heng Feng Two Road, Pu Jin Industrial, Konghou Town, ZhongShan, Guangdong, China
- Phone: 86- 400- 962- 1668
- Fax: 86- 0760- 8841- 3080
- Contact Person (including title): Anna Dan
- E-mail:kamyuen@kyplastic.com

Application Correspondent:

- Company: Guangzhou KEDA Biological Tech Co., Ltd.
- Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhouCity,China
- Contact Person: Mr. Jet Li
- Tile: Regulation Manager
- Tel: +86-18588874857
- Email: med-jl@foxmail.com

2. Subject Device Information

Trade Name:	Aimanfun Lumea Comfort, Model: A-2788
Common Name:	Light based hair removal devices
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

Predicate device I – IV:

Sponsor	CyDen Limited	Shen Zhen CosBeauty Co., Ltd	Conair Corporation	Shaser, Inc.
Device Name	iPulse SmoothSkin Gold Hair Removal System	Perfectsmooth	Lumilisse IPL Hair Remover	Shaser V-MINI RX
510(k) Number	K160968	K161428	K172791	K 132170
Product Code	OHT	OHT	OHT	ONF
Regulation Number	878.4810	878.4810	878.4810	878.4810
Regulation Class	Class II	Class II	Class II	Class II

4. Device Description

Aimanfun Lumea Comfort, Model: A-2788 is a light-based device for long-term hair removal. It is intended for the removal of unwanted hair and permanent reduction in hair regrowth. Ideal body areas include the underarms, bikini line, arms and legs. The device used the IPL technology with lower energy level, including 5 Levels of output energy. Intense Pulsed light technology is able to achieve long-term hair removal results at a fraction of the energy level used in other light-based hair removal equipment.
The size of the device is about 138.9*82*47.3mm (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 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 a pulse emitting.

5. Intended Use / Indications for Use

The Aimanfun Lumea Comfort (Model: A-2788) is indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician，after training by a healthcare professional. The Aimanfun Lumea Comfort 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

Hand-held IPL device (Aimanfun Lumea Comfort) consists of main unit and adaptor. It is a portable device for the permanent reduction of hair growth based on Intense Pulsed Light (IPL) which is a xenon lamp.

The size of the device is about 138.9*82*47.3mm (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 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 a pulse emitting.

7. Materials

There is one part of patient directly contacting component 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 of unit	ABS	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

8. Physical characteristics

Basic Unit Characteristics	
Compliance* with 21 CFR 898	No
Main Unit Weight	200g
Main Unit Dimension	138.9*82*47.3mm
Housing Materials of main unit	ABS
Indicator	Indicates power information/skin detection information, gear conversion information.

Time Range (minutes)	Work for 60 minutes and stop for 10 minutes
Environment for operation	Temperature: 5°C~45°C Humidity: 20~65%
Storage and Transport Conditions	Temperature: 0°C~40°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 Control?	Yes
Specification	
Output Intensity Level	5 steps
Output energy	7-13.5J
Emitted Light Spectrum	475nm~1200nm Max
Pulse width range	3 ms
Power Supply	100-240 VAC, 50/60Hz,0.5A
Technology	IPL

9. Test Summary

Aimanfun Lumea Comfort, Model: A-2788 has been evaluated the safety and performance by lab bench testing as following:

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2012 +A1:2012

IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 2014

IEC 60601-1-11:2015 Medical Electrical Equipment –Part 1: General Requirements for Basic Safety and Essential Performance –Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment

IEC 60601-2-57:2011 Medical electrical equipment –Part 2-57: Particular requirements for the basic safety and essential performance of non-laser source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.

ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff

10. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Aimanfun Lumea Comfort, model: A-2788 is substantially equivalent to the predicate devices quoted above. Aimanfun Lumea Comfort relies on the same technology as both predicate devices : Intense Pulsed Light (IPL). Their energy source is the same: Xenon Arc Flashlamp.

The safety and efficacy of IPL treatment for hair reduction are governed by the following parameters:

• Wavelength of the emitted light (spectrum): Defines the interaction with specific chromophores (the part of the molecule responsible for its color) such as melanin, hemoglobin and water. Aimanfun Lumea Comfort and the predicate devices utilize the same spectrum as the Perfectsmooth predicate device (475-1200nm).

• Fluence/flux – defines the energy per area (e.g. joules per cm^2) for the treatment. Aimanfun Lumea Comfort and the predicate devices deliver the same maximum energy (4.5 joules/cm2).

The following technological differences exist between the subject and predicate devices I to III:

- Prescription use for subject device;
- No Skin tone sensing circuit; but subject device and predicate devices IV is the same design on this feature and both of them are also for prescription use.

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

Elements of Comparison	Subject Device	Primary Predicate Device I	Predicate Device II	Predicate Device III	Predicate Device IV	Verdict
Manufacturer	Kam Yuen Plastic Products Ltd	CyDen Limited.	Shen Zhen CosBeauty Co., Ltd	Conair Corporation	Shaser, Inc.	--
Product Name	Aimanfun Lumea Comfort, Model: A-2788	iPulse SmoothSkin Gold Hair Removal System	Perfectsmooth	Lumilisse IPL Hair Remover	Shaser V-MINI RX	--
510(K) No.	Applying	K160968	K161428	K172791	K 132170	_
Indications for Use	The Aimanfun Lumea Comfort (Model: A-2788) is indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician，after training by a healthcare professional. The Aimanfun Lumea Comfort 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	The iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse SmoothSkin Gold is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs	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 such as legs.	The Lumilisse IPL (Intense Pulsed Light) Hair Remover is an over-the-counter device intended for the removal of unwanted hair.	The Shaser V-MINI RN Hair Removal System is intended to provide phototherapeutic light to the body and is generally indicated to treat dermatological conditions. It is also intended for removal of unwanted hair by using a selective photothermal treatment. The Shaser V-MINI RN Hair Removal System is indicated for patient removal of	SE Note 1

Elements of Comparison	Subject Device	Primary Predicate Device I	Predicate Device II	Predicate Device III	Predicate Device IV	Verdict
	regrowing when measured at 6. 9. and 12 months after the completion of a treatment regimen.	regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.			unwanted hair by using a selective photothermal treatment under the direction of a physician. after training by a healthcare professional. It is also indicated for the removal of unwanted body and/or facial hair in adults with Fitzpatrick skin types I - VI. The Shaser V-MINI RX Hair Removal System 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	

Elements of Comparison	Subject Device	Primary Predicate Device I	Predicate Device II	Predicate Device III	Predicate Device IV	Verdict
					treatment regimen.	
IFU Type	Prescription use	Over-The-Counter	Over-The-Counter	Over-The-Counter	Prescription use	SE Note 2
Classification Product Code	ONF	OHT	OHT	OHT	ONF	SE
Device Type	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light		SE
	Device Design					
Power source	an external power supply	AC Mains	an external power supply	an external power supply	Battery charger	SE
Light source	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	SE
Wavelength	475~1200nm	510nm~1100nm	475nm~1200nm	550-1200 nm	400~1200nm	SE
Spot Size	3.0 cm^2	3 cm^2	4.5 cm^2	About 3 cm^2	2 cm^2	SE
Max. Fluence (J/cm^2)	4.5 J/cm^2	3-6 J/cm^2	4.7 J/cm^2	4.5 J/cm^2	6-10 J/cm^2	SE
Pulse duration	3 milliseconds	2-10 milliseconds	11-13 milliseconds	-	-	SE

Elements of Comparison	Subject Device	Primary Predicate Device I	Predicate Device II	Predicate Device III	Predicate Device IV	Verdict
						Note 3
Output energy	7-13.5 J	9-18 J	< 22 J	6-13.5 J （based on its light intensity 2.0 J cm² -4.5 J/cm²）	< 20 J	SE Note 4
Pulsing Control	Finger switch	Finger switch	Finger switch	Finger switch	Finger switch	SE
Delivery Device	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	SE
Software Control	Yes	Yes	Yes	Yes	Yes	SE
	FDA-Recognized Standards					
Electrical safety, EMC, Biological Evaluation	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 62471 ISO 10993-5 ISO 10993-10 ISO 10993-12	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471 ISO 10993-5 ISO 10993-10	SE

Comparison in Detail(s):

Note 1

Although there is difference about Type of use between Subject device and Predicate device I to III and provide addtional description for using direction requirement that a selective photothermal treatment under the direction of a physician， after training by a healthcare professional. But the type of use of Aimanfun Lumea Comfort is same to predicate device IV(K132170). This difference does not affect the safety and effectiveness.

Note 2

Based on considering mitigates the possibility of intentional misuse of the device on inappropriate skin tones, the subject device was intended to be prescription use for its IFU, referring to K132170. This difference does not affect the safety and effectiveness.

Note 3

Although the pulse duration is minor different to predicate device K161428 Shen Zhen CosBeauty Co., Ltd; but in the predicate device K160968 CyDen Limited, its pulse duration is 2-10 milliseconds, which can cover the pulse duration of 3 ms in subject device. And the photothermolysis treatment mainly is depended on its pulse output energy, and subject device's output energy is substantial equivalent to others predicate device. So the minor difference on pulse duration do not affect the safety and effectiveness.

Note4:

The output energy of subject device is design to be 7- 13.5 J based on its level 1-5; there is minor difference on output energy for the lowest level (Level 1) between subject device and the predicate device K160968 CyDen Limited(9 J); but the lowest level energy also was covered in the output energy range of predicate device III K172791 Conair Corporation. , so the differences do not affect the safety and effectiveness.

Conclusion:

The subject device "Aimanfun Lumea Comfort, Model: A-2788" is substantial Equivalence to all predicate devices.