April 5, 2023

Kam Yuen Plastic Products Ltd.
% Iris Fung
Regulation manager
Guangzhou KEDA Biological Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, Guangdong
China

Re: K230107
Trade/Device Name: Aimanfun Lumea Comfort, Model: A-2788, A-2789 and A-3588
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: January 13, 2023
Received: January 13, 2023

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/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,

Colin K. Chen -S

for

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230107

Device Name
Aimanfun Lumea Comfort, Model: A-2788, A-2789 and A-3588

Indications for Use *(Describe)*
Aimanfun Lumea Comfort is an over-the-counter device intended for removal of unwanted body and/or facial hair.

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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510(k) Summary

K230107

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

1 Submitter Information

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Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China

2 Subject Device Information

Trade Name: Aimanfun Lumea Comfort

Model: A-2788, A-2789 and A-3588

Common Name: Light Based Over-The-Counter Hair Removal

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Review Panel: General & Plastic Surgery

Product Code: OHT

Regulation Number: 878.4810

Regulation Class: 2

3 Predicate device Information

Legally marketed device K190820

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 Number: 878.4810

Regulation Class: 2

Legally marketed device K212907

Trade Name: Aimanfun Lumea Comfort

Model: A-2789, A-3588

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 Number: 878.4810

Regulation Class: 2

Reference device K211185

Common Name: IPL Home Use Hair Removal Device

Model: D-1150, D-1171, D-1153, D-1155, D-1156, D-1126, D-1178, D-1187

Common Name: Light Based Over-The-Counter Hair Removal

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Review Panel: General & Plastic Surgery

Product Code: OHT

Regulation Number: 878.4810

Regulation Class: 2

4 Device Description

Aimanfun Lumea Comfort, Model: A-2788, A-2789 and A-3588 is an over-the-counter use device for the reduction of hair growth. Ideal body areas include the underarms, bikini line, arms and legs. The device used the Intense Pulsed Light (IPL) technology with lower energy level, including 5 Levels of output energy. Intense Pulsed light technology is able to achieve hair removal results at a fraction of the energy level used in other light-based hair removal equipment.

The hand-held device package includes main unit, adaptor and user manual and it uses a Xenon Lamp to emit specified wavelength pulsed light to heat the root where the hair grows, and a skin proximity sensor to detect appropriate skin contact. If the 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

Aimanfun Lumea Comfort is an over-the-counter device intended for removal of unwanted body and/or facial hair.

6 Complied Standards

Aimanfun Lumea Comfort, Model: A-2788, A-2789 and A-3588 complies with the following FDA recognized consensus standards:

- IEC 60601-1: 2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

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

7 Device modification description

The only modification of subject device is Intended Use. The device has changed to over-the-counter use. Therefore, the User Manual and Box labelling has been adding corresponding use instructions for lay person user.

8 Performance Testing

As the modification of subject device as above, results in no technological characteristics changes, the tests and data utilized to demonstrate safety and efficacy of the predicate device (legally existing device) are suitable for use in the assessment of the subject devices except for usability study verification. In usability study, the testing result demonstrates that the intended users can understand the package labeling, correctly choose the device and use it for the indicated OTC use, based on reading the lableling materials.

As there have been no changes to the performance of the subject device from the predicate

device, this submission leverages performance and electrical testing provided in previous submission.

9 Biocompatibility

All the modified device materials which come in direct contact with the patient skin are biocompatible and identical to the materials used in the predicate device manufacturing. No biocompatibility test report is provided in this submission.

10 Clinical performance

Clinical performance is not deemed necessary.

11 Comparison with predicate device

Compare with predicate device (Aimanfun Lumea Comfort, K190820 and K212907), the subject device is same in design principle, functions, material and the applicable standards. The differences between subject device and predicate devices do not raise any new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1		Predicate Device 2
Manufacturer	Kam Yuen Plastic Products Ltd.	Kam Yuen Plastic Products Ltd.		Kam Yuen Plastic Products Ltd.
Product Name	Aimanfun Lumea Comfort	Aimanfun Lumea Comfort		Aimanfun Lumea Comfort
Model	A-2788, A-2789 and A-3588	A-2789	A-3588	A-2788
510(K) No.	K230107	K212907		K190820
Indications for Use	Aimanfun Lumea Comfort is an over-the-counter device intended for removal of unwanted body and/or facial hair.	The Aimanfun Lumea Comfort (Model: A-2789, A-3588) 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.		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.

Elements of Comparison	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**
		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.	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	Over-The-Counter Use	Prescription use	Prescription use
Classification Product Code	OHT	ONF	ONF
Technology	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light
Device Type	Hand-held	Hand-held	Hand-held
Status display	A-2788: LED indicators A-2789: LCD screen A-3588: LCD screen	LCD screen	LED indicators
Work mode	A-2788: Single flash mode A-2789: Single flash mode, Sliding	Single flash mode Sliding flash mode	Single flash mode

Elements of Comparison	**Subject Device**	**Predicate Device 1**		**Predicate Device 2**
	flash mode A-3588: Single flash mode, Sliding flash mode			
Ice-sensing function	A-2788: No A-2789: No A-3588: Yes	No	Yes	No
Power source	External power supply	External power supply		External power supply
Light source	Xenon Arc Flashlamp	Xenon Arc Flashlamp		Xenon Arc Flashlamp
Wavelength	475~1200nm	475~1200nm		475~1200nm
Spot Size	3.0 cm^2	3.0 cm^2		3.0 cm^2
Max. Fluence	4.5 J/cm^2	4.5 J/cm^2		4.5 J/cm^2
Pulse duration	3 milliseconds	3 milliseconds		3 milliseconds
Output energy	7-13.5 J	7-13.5 J		7-13.5 J
Pulsing Control	Finger switch	Finger switch		Finger switch
Delivery Device	Direct Illumination to Tissue	Direct Illumination to Tissue		Direct Illumination to Tissue

Elements of Comparison	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**
Software Control	Yes	Yes	Yes
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 60601-1-11 IEC 60601-2-57 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 ISO 10993-5 ISO 10993-10

12 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the subject device Aimanfun Lumea Comfort is to be concluded substantial equivalent to its predicate device.

13 Summary Prepared Date

Apr 04, 2023