December 2, 2021

Kam Yuen Plastic Products Ltd.
% Jett Lee
Regulation manager
Guangdong Jianda Medical Technology Co Ltd
906 Room, Longxiang Garden, Tianhe District
Guangzhou, Guangdong
China

Re: K212907
Trade/Device Name: Aimanfun Lumea Comfort, A-2789/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: ONF
Dated: October 29, 2021
Received: November 3, 2021

Dear Jet Lee:

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
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)*
K212907

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

Indications for Use *(Describe)*
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. 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 requirements of 21 CFR 807.92.

1 Submitter Information

Sponsor: Kam Yuen Plastic Products Ltd.
Establishment Registration Number: 10078856
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: Anna Dan
E-mail: kamyuen@kyplastic.com

Application Correspondent: Jett Lee
Company: Guangdong Jianda Medical Technology Co., Ltd
E-mail: jianda-lee@foxmail.com
Phone: 86-13512755282
Address: 906 Room, Longxiang Garden, Tianhe district, Guangzhou, China

2 Subject Device Information

Type of 510(k) submission: Special 510(k): Device Modification
Common Name: Light based hair removal devices
Trade Name: Aimanfun Lumea Comfort
Model: A-2789, A-3588
Classification Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Review Panel: General & Plastic Surgery
Product Code: ONF
Regulation Number: 21 CFR 878.4810
Regulation Class: 2

3 Legally marketed device (predicate device) Information

Common Name: Light based hair removal devices
Trade Name: Aimanfun Lumea Comfort
Model: A-2788
510K Number: K190820
Classification Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Review Panel: General & Plastic Surgery
Product Code: ONF
Regulation Number: 21 CFR 878.4810

Regulation Class: 2

4 Device Description

Aimanfun Lumea Comfort is a light-based device for long-term hair removal, designed for home environment used. 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 device 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.

The device is a home-use and hand-held device consisted of consists of main unit and adaptor, for the permanent reduction of hair growth based on Intense Pulsed Light (IPL).

5 Intended Use

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. 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 Complied Standards

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

- ☒ 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

7 Device modification description

All the modifications of subject device are shown in the following table as below, and no other changes were made to legally existing predicate device.

Design modification	Before modification	After modification	
Model name	**A-2788**	**A-2789**	**A-3588**
Appearance			
Structure and Buttons	Skin Contact Window Integrated UV filter Energy Level Indicator Ready Lamp Power Adapter	Skin Contact Window Integrated UV filter LCD Screen Power Adapter	Skin Contact Window Integrated UV filter LCD Screen Power Adapter Indicator Light
	5-level Button Flash Key	ON/OFF Button Flash Key	ON/OFF Button ICE Button Flash Key
Work mode	Single flash mode	Single flash mode Sliding flash mode	Single flash mode Sliding flash mode
Ice-sensing function	No	No	Yes
Dimensions W*D*H	82×138.9×47.3(mm)	82×138.9×47.5(mm)	74×135×233(mm)
Weight	200g	241g	360g

8 Performance Testing

As the modifications 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 are suitable for use in the assessment of the subject device. So this submission leverages performance and electrical testing provided in previous submissions.

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. This

submission leverages biocompatibility test report provided in previous submissions.

10 Clinical performance

Clinical performance is not deemed necessary.

11 Comparison with predicate device

Compare with predicate device, the subject device is very similar in design principle, intended use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.

Elements of Comparison	Subject Device		Predicate Device	Verdict
Manufacturer	Kam Yuen Plastic Products Ltd		Kam Yuen Plastic Products Ltd	--
Product Name	Aimanfun Lumea Comfort		Aimanfun Lumea Comfort	--
Model	A-2789	A-3588	A-2788	
510(K) No.	TBD		K190820	_
Indications for Use	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. 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 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.	SE
IFU Type	Prescription use	Prescription use	Prescription use	SE
Classification Product Code	OHT/ONF	OHT/ONF	OHT/ONF	SE
Technology	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	SE
Device Design				
Device Type	Hand-held	Hand-held	Hand-held	SE
Status display	LCD screen	LCD screen	LED indicators	SE Note 1
Work mode	Single flash mode Sliding flash mode	Single flash mode Sliding flash mode	Single flash mode	SE Note 2
Ice-sensing function	No	Yes	No	SE Note 3
Power source	External power supply	External power supply	External power supply	SE

Elements of Comparison	Subject Device		Predicate Device	Verdict
Light source	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	SE
Wavelength	475~1200nm	475~1200nm	475~1200nm	SE
Spot Size	3.0 cm2	3.0 cm2	3.0 cm2	SE
Max. Fluence	4.5 J/cm²	4.5 J/cm²	4.5 J/cm²	SE
Pulse duration	3 milliseconds	3 milliseconds	3 milliseconds	SE
Output energy	7-13.5 J	7-13.5 J	7-13.5 J	SE
Pulsing Control	Finger switch	Finger switch	Finger switch	SE
Delivery Device	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	SE
Software Control	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 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	SE

Note 1

Although the subject device utilizes a LCD screen instead of indicator lamps to display device status, such as Device On/Off, Output Energy Level, Flash Ready/Recharging and Lamp lifetime, those do not result in a change in functionality and technical specification. So the difference does not affect the safety and effectiveness.

Note 2

Although the subject device provides extra sliding flash mode, which is only to trigger IPL flash continuously, instead of manually trigger under single flash mode. The difference does not result in a change of IPL technical specifications, so the difference does not affect the safety and effectiveness.

Note 3

Although the subject device (model: A-3588) provides an ice-sensing function, which utilizes a thermoelectric cooler under the skin contact window, the function is only to make patients comfortable with slightly cool sensation after IPL treatment, and have no therapeutic effect. The difference does not result in a change of IPL technical specifications, so the difference does not affect the safety and effectiveness.

Conclusion

The subject device has all features of the predicate device for intended use. Thus, the subject device is substantially equivalent to the predicate device.

12 Summary Prepared Date: 10 Mar. 2021