September 24, 2021

Shenzhen Accompany Technology Co., Ltd.
℅ Jett Lee
Official Correspondent
Guangdong Jianda Medical Technology Co Ltd
906 Room, Longxiang Garden, Tianhe District
Guangzhou, Guangdong
China

Re: K212099
Trade/Device Name: Red Wave Hair Removal
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: June 28, 2021
Received: July 6, 2021

Dear Jett 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)*
K212099

Device Name
Red Wave Hair Removal, Model:ARH001

Indications for Use *(Describe)*
The Red Wave Hair Removal Device 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 device is also indicated for the permanent reduction in hair regrowth, 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 regime. The device is used for adults.

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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Date of the summary prepared: September 22, 2021

510(k) Summary

510(k) number: K212099

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: Shenzhen Accompany Technology Co., Ltd.
- Address: Unit. 375, Xiangnan Ruifeng Gradan, No. 22,Guimiao Road, Xuefu Community, Nanshan Street, Nanshan District, Shenzhen, Guangdong, China.
- Phone: 86-075522674547
- Contact Person (including title): Ms. Yourong Lai (Regulation engineer)
- E-mail: laiyourong@accompany.tech

Application Correspondent:

- Company: Guangdong Jianda Medical Technology Co Ltd
- Address: 906 Room, Longxiang Garden, Tianhe district, Guangzhou, China
- Contact name: Jett Lee
- Email: jianda-lee@foxmail.com
- Phone: 13512755282

2. Subject Device Information

Trade Name:	Red Wave Hair Removal, Model: ARH001
Common Name:	Light Based Prescription-Use Hair Removal
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	CyDen Limited.	Conair Corporation	Kam Yuen Plastic Products Ltd.
Device Name	Ipulse Smoothskin Gold Hair Removal Device	Lumilisse IPL Hair Remover	Aimanfun Lumea Comfort
510(k) Number	K160968	K172791	K190820
Product Code	OHT	OHT	ONF
Regulation Number	878.4810	878.4810	878.4810
Regulation Class	2	2	2

4. Device Description

Red Wave Hair Removal, Model: ARH001, is a small prescription-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. It is a personal Light-Based Hair Removal System. 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. Emission activation is by finger switch. Device includes IPL DEVICE, Power supply and User manual. It is used AC Powered (100-240 V AC). The weight of the device is 285g, and the size is 152.9×101.5×94.8mm (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 Red Wave Hair Removal Device 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 device is also indicated for the permanent reduction in hair regrowth, 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 regime. The device is used for adults.

6. Design

The device works in exactly the same way as professional IPL devices used by salons and clinics. 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 re-growing. 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 Red Wave 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. Body lamp cartridge can be used for body hair below the neck. It can cover an area of 2.7 cm², and it is specially designed for large areas on underarms, bikini line, arms and legs. It can remove hair in a large scope rapidly. Do not use Body lamp cartridge on the areas around eyes or near eyelid. The product can flash for 50,000 times, and when the flash time comes to 50000 times, all five lamps of energy level indicators will flash when power on the device and it would not be operable.

7. Materials

There is one part of patient- 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)
IPL Lamp output window	ABS: PC2805	Surface-contacting device: skin	Maximum 30 minutes(< 24hours)

We provide ISO 10993-5, -10 test reports for the following biocompatibility evaluation.

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity

8. Physical characteristics

Basic Unit Characteristics	
Compliance* with 21 CFR 898	N/A
Main Unit Weight	285 g
Main Unit Dimension	152.9*101.5*94.8 mm(H*W*D)
Housing Materials of main unit	ABS+PC
Indicator	Indicates power information, intensity level information.
Environment for operation	Temperature: 5°C~35°C Relative 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
Output energy	5.4-13.5J

Emitted Light Spectrum	620nm~1200nm Max
Max Energy density	Up to 5.0 J/cm²
Treatment Area	2.7 [cm²]
Max number of Flashes:	50000 times
Power Supply	100-240 VAC, 50/60Hz
Technology	IPL

10. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Red Wave Hair Removal, Model: ARH001 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 I	Predicate Device II	Predicate Device III
Device Name and Model	Red Wave Hair Removal, Model: ARH001	iPulse SmoothSkin Gold	Lumilisse IPL Hair Remover	Aimanfun Lumea Comfort (Model: A-2788)
510(k) Number	K212099	K160968	K172791	K190820
Manufacturer	Shenzhen Accompany Technology Co., Ltd.	CyDen Ltd	Conair Corporation	Kam Yuen Plastic Products Ltd.
Intended Use	The Red Wave Hair Removal Device 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 device is also indicated for the permanent reduction in hair regrowth, defined as the long-term,	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 regrowing when measured at 6, 9 and 12 months	The Lumilisse IPL (Intense Pulsed Light) Hair Remover is an over-the-counter device intended for the removal of 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

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Predicate Device III
	stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime. The device is used for adults.	after the completion of a treatment regime.		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.
Source Energy	Supplied by external adapter	Supplied by external adapter	Supplied by external adapter	Supplied by external adapter
'Use' Classification	Prescription use	OTC	OTC	Prescription use
Device Classification	Class II	Class II	Class II	Class II
Device Type	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light
Wavelength (nm)	620nm~1200nm	510nm~1100nm	550-1200 nm (when using with body lens) 600-1200 nm (when using with facial lens)	475~1200nm
Max. Fluence (J/cm^2)	Max 5.0 [Joules/cm^2]	Max 6 [Joules/cm^2]	4.5[Joules/cm^2]	Max 4.5 [Joules/cm^2]
Spot Size (cm^2)	2.7 cm^2	3 cm^2	--	3.0 cm^2
Light Intensity	2.0 -5 J/cm^2	3-6J/cm2	Level 1: 2.0 J/cm^2 Level 2: 3.0 J/cm^2 Level 3: 3.5 J/cm^2 Level 4: 4.0 J/cm^2 Level 5: 4.5 J/cm^2	--
Pulse duration	10.0ms ± 1.0ms	2-10 ms	--	3 milliseconds

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Predicate Device III
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Pulsing Control	Finger switch	Finger switch	Finger switch	Finger switch
Number of Output Channels	One channel	One channel	One channel	One channel
Output Intensity Level	5 levels	5 levels	5 levels	5 levels
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes
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	Yes Comply with IEC 60601-1 and IEC 60601-1-2,IEC60601-2-57
Compliance* with 21 CFR 898	No	No	No	No
Weight	285g	--	--	200g
Dimensions	152.9*101.5*94.8 mm(H*W*D)	--	--	138.9*82*47.3mm(H*W*D)
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.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.
Electrical Safety	Comply with IEC60601-1 and IEC60601-2-57	Comply with IEC 60601-1 and IEC 60601-2-57	Comply with IEC 60601-1 and IEC 60601-2-57	Comply with IEC 60601-1 and IEC 60601-2-57

11. Test Summary

Red Wave Hair Removal, Model: ARH001 has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1: 2005+COR1:2006+COR2:2007+AMD1:2012 and IEC 60601-2-57: 2011 standards

- Electromagnetic compatibility test according to IEC 60601-1-2: 2014 standard
- Software verification and validation test according to the requirements of the FDA “Guidance for PreMarket Submissions and for Software Contained in Medical Devices” 2005”

12. Conclusion:

The subject device “Red Wave Hair Removal, Model: ARH001” is substantially equivalent to all predicate devices.