October 4, 2021

Shenzhen Mywin Technology Co., Ltd.
℅ Jet Li
Regulation Manager
Guangzhou KEDA Biological Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
GuangZhou, Guangdong
China

Re: K211368
Trade/Device Name: IPL Hair Remover, Model: G993, G996, G998 and G885
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: September 3, 2021
Received: September 13, 2021

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 and Part 809); 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 U. Pandya -S

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)*
K211368

Device Name
IPL Hair Remover, Model: G993, G996, G998 and G885

Indications for Use *(Describe)*
The IPL Hair Remover Device, Model: G993, G996, G998 and G885 is indicated for the removal of unwanted hair 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.

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Date of the summary prepared: June 11, 2021

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: Shenzhen Mywin Technology Co., Ltd.
- Address: 2nd Floor, Building B, New Age gongrong Industrial Zone, No. 2, Shihuan Road, Shilong community, Shiyan Street, Baoan District, Shenzhen 518103,China
- Phone: +86-18902842323
- Contact Person: Meiyun Liu
- E-mail: Szmywin@163.com

Application Correspondent:

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

2. Subject Device Information

♦ Trade Name:	IPL Hair Remover, Model: G993, G996, G998 and G885
♦ Common Name:	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
♦ Classification name:	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
♦ 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
Regulation Number	878.4810	878.4810	878.4810
Regulation Class	2	2	2

4. Device Description

IPL Hair Remover, Model: G993, G996, G998 and G885 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 215.1g, and the size is 188 x 76 x 49mm (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. Indications for Use

The IPL Hair Remover Device (Model: G993, G996, G998 and G885) is indicated for the removal of unwanted hair 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. Test Summary

IPL Hair Remover, Model: G993, G996, G998 and G885 has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1, IEC60601-1-11 and IEC 60601-2-57 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- 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.

- Software verification and validation test according to the requirements of the FDA "Guidance for PreMarket Submissions and for Software Contained in Medical Devices"

Clinical testing: No clinical trial is necessary in the submission.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of IPL Hair Remover, Model: G993, G996, G998 and G885 is the same or similar 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	Remark
Device Name and Model	IPL Hair Remover, Model: G993, G996, G998 and G885	Ipulse Smoothskin Gold Hair Removal Device	Lumilisse IPL Hair Remover	Aimanfun Lumea Comfort (Model: A-2788)	--
510(k) Number	Applying	K160968	K172791	K190820	--
Manufacturer	Shenzhen Mywin Technology Co., Ltd.	CyDen Limited.	Conair Corporation	Kam Yuen Plastic Products Ltd.	--
Indications for Use	The IPL Hair Remover Device (Model: G993, G996, G998 and G885) is indicated for the removal of unwanted hair 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	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 after the completion of a treatment regime.	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 permanent reduction in unwanted hair. Permanent hair reduction is defined	Similar Note 1

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Predicate Device III	Remark
	treatment regime. The device is used for adults.			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	Same Note 2
'Use' Classification	Prescription use	OTC	OTC	Prescription use	Same Note 3
Device Classification	Class II	Class II	Class II	Class II	Same
Device Type	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Wavelength (nm)	510nm~1100nm	510nm~1100nm	550-1200 nm (when using with body lens) 600-1200 nm (when using with facial lens)	475~1200nm	Similar Note 4
Max. Fluence (J/cm^2)	Max 4.5 [Joules/cm^2]	Max 6 [Joules/cm^2]	4.5[Joules/cm^2]	Max 4.5 [Joules/cm^2]	Same
Spot Size (cm^2)	4.3 cm^2	3 cm^2	--	3.0 cm^2	Similar Note 5
Light Intensity	Level 1: 1.8 J/cm^2 Level 2: 2.3 J/cm^2 Level 3: 3.2 J/cm^2 Level 4: 4.4 J/cm^2 Level 5: 4.5 J/cm^2	3-6 J/cm^2	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	2.5-4.5 J/cm^2	Similar Note 6
Pulse duration	3 ms	2-10 ms	--	3 milliseconds	Similar Note 7
Energy medium	Xenon Arc	Xenon Arc	Xenon Arc	Xenon Arc	Same

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Predicate Device III	Remark
	Flashlamp	Flashlamp	Flashlamp	Flashlamp	
Pulsing Control	Finger switch	Finger switch	Finger switch	Finger switch	Same
Number of Output Channels	One channel	One channel	One channel	One channel	Same
Output Intensity Level	5 levels	5 levels	5 levels	5 levels	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes	Same
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	Same
Compliance* with 21 CFR 898	No	No	No	No	Same
Weight	215.1g	--	--	200g	Similar Note 2
Dimensions	188*76*49 mm(H*W*D)	--	--	138.9*82*47.3mm(H*W*D)	Similar Note 2
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.	Same
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	Same

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 additional description for using direction requirement under the direction of a

physician, after training by a healthcare professional. But the type of use of IPL Hair Remover is same to predicate device III (K190820). This difference does not affect the safety and effectiveness.

Note 2:

"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 3:

Although there is difference about Type of use between Subject device and supplement device，the subject device provide additional description for using direction requirement that a selective photothermal treatment under the direction of a physician， after training by a healthcare professional. And the type of use of subject device is same to predicate device III (Prescription for use) referring to K190820. This difference does not affect the safety and effectiveness.

Note 4:

Although the wavelength of subject device is a little different from the predicate devices, but they all comply with IEC 60601-1, IEC 60601-2-57 requirement.

And the wavelength of subject device is same with that of predicted device I, and in the range of both predicted device I and predicted device III. So we believe that the wavelength (510-1100 nm) is effective in hair removal application and its safety is acceptable.

So the differences of wavelength will not raise any safety or effectiveness issue.

Note 5:

The types of "Spot Size (cm^2)" of subject device, and there is minor difference between the subject device and the predicate devices. The spot size only affect the treatment skin area at one shot of flash. It do not affect the safety and effectiveness of the device. And they all comply with IEC 60601-1, IEC60601-2-57 requirement.

So the differences of Spot size will not raise any safety or effectiveness issue.

Note 6:

For "Light Intensity in each level" of subject device, and there is minor difference between the subject device and the predicate device I. But the light intensity of subject device is same to the predicate device II and predicate device III. So we believe that the light intensity (1.8-4.5 J/cm^2)

is effective in hair removal application and its safety is acceptable. And they all comply with IEC 60601-1, IEC60601-2-57 requirement.

So the differences of light intensity will not raise any safety or effectiveness issue.

Note 7
Although the pulse duration is minor different to predicate device I; but in the predicate device III (K190820), its pulse duration is 3 milliseconds, which is identical to 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.

Finial Conclusion:
Based on the nonclinical testing conducted, the subject device "IPL Hair Remover, Model: G993, G996, G998 and G885" is the same or similar to all predicate devices, as safe, as effective, and performs as well as the legally marketed predicate devices.