July 7, 2022

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: K221679
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: OHT
Dated: June 8, 2022
Received: June 9, 2022

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,

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)*
K221679

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

Indications for Use *(Describe)*
IPL Hair Remover 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary - K221679

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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Application Correspondent: Jet Li

Company: Guangzhou KEDA Biological Technology Co., Ltd

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Phone: 86-18588874857

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

2 Subject Device Information

Type of 510(k) submission: ***Special 510(k) Device Modification***

Common Name: IPL Hair Remover

Model: G993, G996, G998 and G885

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 existing device K211368

Company Name:

Common Name: IPL Hair Remover

Model: G993, G996, G998 and G885

Common Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect

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

IPL Hair Remover Device (Model: G993, G996, G998 and G885), is an over-the-counter use device for removal of unwanted body and/or facial hair based on Intense Pulsed Light

(IPL) treatment. The device package includes IPL DEVICE, Power supply and User manual. It is supplied by AC power supply (Input 100-240 V AC). The weight of the device is 215.1g, and the size is 188 × 76 × 49mm.The device incorporates Intense Pulse Light (IPL) technology. The purpose of the light is to heat the root where the hair grows.

The device is equipped with a Xenon Lamp and a skin proximity sensor to detect appropriate skin contact. If the IPL Hair Remover Device is not properly applied to the treatment area (in full contact with the skin), the device cannot be triggered for pulse emitting. The device can be used for large areas on legs, arms, back and abdomen. The product can flash for 100,000 times. .

5 Intended Use

IPL Hair Remover is an over-the-counter device intended for removal of unwanted body and/or facial hair.

6 Complied Standards

IPL Hair Remover G993, G996, G998 and G885 complies with the following FDA recognized consensus standards:

- ☒ 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.

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.

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 (IPL Hair Remover K211368), the subject device is same in design principle, functions, material and the applicable standards. And the intended use of subject device is same to Reference device K211185. The differences between subject device and predicate devices do not raise any new questions of safety or effectiveness.

Item	Subject Device	Predicate Device	Reference Device
Manufacturer	Shenzhen Mywin Technology Co., Ltd.	Shenzhen Mywin Technology Co., Ltd.	Shenzhen Beauty Every Moment intelligent electric Co.,Ltd.
K number	TBD	K211368	**K211185**

Product Name	IPL Hair Remover G993, G996, G998 and G885	IPL Hair Remover G993, G996, G998 and G885	IPL Home Use Hair Removal Device D-1150, D-1171, D-1153, D-1155, D-1156, D-1126, D-1178, D-1187
Regulation & Classification	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	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	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
Indications for Use	IPL Hair Remover is an over-the-counter device intended for removal of unwanted body and/or facial hair.	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	IPL Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair.

		completion of a treatment regime. The device is used for adults.	
	OTC Use	Prescription Use	OTC Use
Source Energy	Supplied by external adapter	Supplied by external adapter	Supplied by external adapter
Device Type	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light
Wavelength (nm)	510nm ~ 1100nm	510nm ~ 1100nm	Regular window: 530-1100nm, 590-1100nm Filter window: 600-1100nm
Max. Fluence	Max 4.5 J/cm^2	Max 4.5 J/cm^2	Max 4.5 J/cm^2
Spot Size	4.3 cm^2	4.3 cm^2	4.3 cm^2
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	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	2.0 to 4.5 J/cm^2
Pulse duration	3 ms	3 ms	7.5~12 ms
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Pulsing Control	Finger switch	Finger switch	Finger switch
Number of Output Channels	One channel	One channel	One channel
Output Intensity Level	5 levels	5 levels	/
Software Control?	Yes	Yes	/
Weight	215.1g	215.1g	/
Dimensions	188*76*49 mm (H*W*D)	188*76*49 mm (H*W*D)	/
Electrical	IEC 60601-1	IEC 60601-1	IEC 60601-1

safety, EMC	IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-57	IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-57	IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57
Biocompatibility	ISO10993-5 ISO10993-10	ISO10993-5 ISO10993-10	ISO10993-5 ISO10993-10

Note

Although the indication for use of subject device is different to predicate device K211368, but it is only to simplify the statement of the legally existing predicate device and remove the prescription use statement, which is not involved with technical specifications. The revised indication for use of subject device in this submission also had been covered by the indication for use of the legally existing predicate device; which is same to ***Reference device K211185***. And the subject device had been verify by usability study for its OTC use. So the difference does not affect the safety and effectiveness.

12 Summary Prepared Date

28 Jun. 2022