September 14, 2023

Shenzhen Wochuan Electronic Co., Ltd
% Tracy Che
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K232124
Trade/Device Name: IPL Hair Removal, Model: W-1095, W-1098
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: July 12, 2023
Received: July 17, 2023

Dear Tracy Che:

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 -S

Digitally signed by Jianting Wang -S
Date: 2023.09.14 16:11:07 -04'00'

For Tanisha Hithe, MS, MHS
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)*
K232124

Device Name
IPL Hair Removal, Model: W-1095, W-1098

Indications for Use *(Describe)*
IPL Hair Removal 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 K232124

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	Shenzhen Wochuan Electronic Co., Ltd
Address:	6th Floor Building No.357 3rd Area A Huayuan Xingye 1 road, Fenghuang Community, Fuyong Street, Baoan District, Shenzhen, Guangdong China
Contact person:	Rebecca Jiang
Phone number:	+86 13823355685
Fax number:	/
Email:	rebecca@szwoc.com
Date of summary prepared:	2023-07-12

(2) Reason for the submission

New device, there were no prior submissions for the device.

(3) Proprietary name of the device

Trade name/model:	IPL Hair Removal, Model: W-1095, W-1098
Common name:	Light Based Over-The-Counter Hair Removal
Regulation number:	21 CFR 878.4810
Product code:	OHT
Review panel:	General & Plastic Surgery
Regulation class:	Class II

(4) Predicate and reference devices

- **Predicate devices**

	Primary predicate device	**Predicate device**
Sponsor	Shenzhen Junbobeauty Technology Co., Ltd.	Shenzhen Bosidin Technology Co.,Ltd.
Device Name and Model	IPL HAIR REMOVAL HANDSET Model: IPL-666	IPL Home Use Hair Removal Device Model(s): D-1128, D-1103, D-1119, D-1129, D-1130
510(k) Number	K220669	K192432
Product Code	OHT	OHT

Regulation Number	21 CFR 878.4810	21 CFR 878.4810
Regulation Class	II	II

- **Reference device**

Sponsor	Glan Electronics Co., Ltd.
Device Name and Model	IPL Hair Removal, Model: OBT-02
510(k) Number	K213041
Product Code	OHT
Regulation Number	21 CFR 878.4810
Regulation Class	II

(5) Description/ Design of device:

The IPL Hair Removal is a personal, light-based, hair reduction device intended to be sold over-the-counter directly to the end user. The device provides hair reduction using Intense Pulsed Light (IPL) technology. It works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain. The device is only powered by the external power adapter and its IPL emission activation is by finger switch. The device contains Xenon Lamp to emit light and skin 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 trigger a pulse. The IPL Hair Removal includes two models, W-1095 and W-1098. The two models are the same in intended use, working principle, the main differences are appearance and output parameters.

(6) Indications for use:

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

(7) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
IPL Hair Removal (Model: W-1095)	ABS+PS	Surface-contacting device: Intact skin	Less than 24 hours
IPL Hair Removal (Model: W-1098)	ABS	Surface-contacting device: Intact skin	Less than 24 hours

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to "Biocompatibility Discussion".

(8) Technological characteristics and substantial equivalence:

Item	Subject device	Primary predicate device	Predicate device	Reference device	Remark
Trade name	IPL Hair Removal, Model W-1095, W-1098	IPL HAIR REMOVAL HANDSET Model: IPL-666	IPL Home Use Hair Removal Device Model(s): D-1128, D-1103, D-1119, D-1129, D-1130	IPL Hair Removal, Model: OBT-02	/
510 (k) number	Applying	K220669	K192432	K213041	/
Manufacturer	Shenzhen Wochuan Electronic Co., Ltd	Shenzhen Junbobeauty Technology Co., Ltd.	Shenzhen Bosidin Technology Co., Ltd.	Glan Electronics Co., Ltd.	/
Regulation number	21CFR 878.4810	21CFR 878.4810	21CFR 878.4810	21CFR 878.4810	Same
Product code	OHT	OHT	OHT	OHT	Same
Class	II	II	II	II	Same
Indications for use/ Intended use	IPL Hair Removal is an over-the-counter device intended for removal of unwanted body and/or facial hair.	IPL HAIR REMOVAL HANDSET is an over-the-counter device intended for removal of unwanted body and/or facial hair.	IPL Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair.	The IPL Hair Removal Device OBT-02 Version is indicated for the removal of unwanted hair. 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.	Same
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Applicable	Fitzpatrick Skin	Fitzpatrick Skin	Fitzpatrick Skin	Unknown	Same

skin	Phototypes I-V	Phototypes I-V	Phototypes I-V		
Treatment area	Multiple hair removal areas, including small areas (e.g. armpit, bikini lines) and large areas (e.g. arms, legs).	The device is designed for use on the legs, underarms, bikini line, chest, stomach, back, arms and on the face below the cheekbones.	Removal of unwanted body hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs.	Unknown	Similar
Device design					
Power source	An external power supply	An external power supply	Supplied by external power adapter	Supplied by external adapter	Same
Power supply	100~240V AC Input DC 12V 3A Output	100~240V AC Input 12V3A DC Output	Input: 100-240V 50/60Hz 1.0-0.5A Output: DC12V 3A	100-240 V AC	Same
Product compositions	IPL Hair Removal main device and power adapter	IPL Hair Removal Handset and power adapter	IPL host, lamp cartridge and power adapter	IPL device and power supply	Similar
Structure design	Handheld	Handheld	Handheld	Handheld	Same
Dimension	W-1095:163*60*37mm W-1098:170.5*68.5*43mm	124*83*48.5mm	218 x 144 x 60mm	150*75*45mm (H*W*D)	Different
Weight	W-1095:≈223.5g W-1098:256.92g	186g	355g	220g	Different
Sterilization	Not required	Not required	Not required	Not required	Same
Output specification					
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc flashlamp	Xenon Quartz Tube	Xenon lamp	Xenon Arc Flashlamp	Same
Wavelength range (nm)	470nm ~1100nm	470nm ~1100nm	Regular window: 510 ~ 1100nm Filter window: 600 ~ 1100nm	510nm~1100nm	Same
Energy density (J/cm^2)	W-1095:1.67~4.46J/cm^2 W-1098:1.16~2.79J/cm^2	1.3-2.49J/cm^2	2.0~4.0J/cm^2 (applicable for model D-1128, D-1119, D-1129, D-1130) 2.5~4.5J/cm^2 (Applicable for model D-1103)	1.5-4.0J/cm^2	Similar
Spot size	W-1095: 2.69cm^2	3cm^2	Regular window:	3.0cm^2	Similar

(Size of treatment window) (cm^2)	W-1098: 4.3cm^2		4.5cm^2, 2.0cm^2, 3.0cm^2 Filter window: 2.5cm^2		
Pulse duration	4-13ms	11.5-15ms	7.5-14ms	3ms	Similar
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Number of output channels	One channel	One channel	One channel	One channel	Same
Output intensity level	W-1095: 5 levels W-1098: 3 levels	5 levels	5 levels	5 levels	Similar
Skin sensor	Sensor fixed in device and can be moved to treatment part	Sensor fixed in handset and can be moved to treatment part	Sensor fixed in device and can be moved to treatment part	Sensor fixed in device and can be moved to treatment part	Same
Software/ Firmware/ Microprocessor or Control?	Yes	Yes	Yes	Yes	Same
Additional features					
Skin-contacting components	Enclosure and light outlet	Plastic enclosure and treatment window	Plastic enclosure and treatment window	Enclosure and treatment window	Same
Materials of skin-contacting components	ABS, PS	Plastic, metal	ABS, PC, Aluminium alloy	Unknown	Different
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	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-83	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-83	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	Same

Photobiological safety	IEC62471	IEC62471	IEC62471	Unknown	Same

(9) Non-clinical studies and tests performed:

Non-clinical testings have been conducted to verify that the IPL Hair Removal meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate devices. The testing results demonstrate that the subject device complies with the following standards:

- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11, Medical electrical equipment - Part 1-11: 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 60601-2-83, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 62471, Photobiological safety of lamps and lamp systems

The device has been tested for biocompatibility, it complies with the following standards.

- ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

We have also conducted:

- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"
- Usability evaluation according to the requirements of the FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016"

(10) Conclusion

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device IPL Hair Removal is as safe, as effective, and performs as well as the legally marketed predicate devices and reference device.