May 16, 2022

Shenzhen Junbobeauty Technology 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: K220669
Trade/Device Name: IPL HAIR REMOVAL HANDSET, Model: IPL-666
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: February 25, 2022
Received: March 7, 2022

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,

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)*
K220669

Device Name
IPL HAIR REMOVAL HANDSET, Model: IPL-666

Indications for Use *(Describe)*
IPL HAIR REMOVAL HANDSET 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

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 Junbobeauty Technology Co., Ltd.
Address:	#522, Jinyuan Business Building A, Xixiang Blvd 300, Bao'an District, Shenzhen
Contact person:	Jian Zhan
Phone number:	+86 17665318870
Fax number:	/
Email:	779182481@qq.com
Date of summary prepared:	2022-2-25

(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 HANDSET, Model: IPL-666
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 device

- **Predicate device**

Sponsor	Medical Device Branch of Zhangzhou Easepal Industrial Co.,Ltd.
Device Name and Model	IPL Salon Hair Reduction System, Model: F60001
510(k) Number	K181568
Product Code	OHT
Regulation Number	21 CFR 878.4810
Regulation Class	II

- **Reference device**

Sponsor	Shenzhen Bosidin Technology Co. Ltd.
Device Name and Model	IPL Home Use Hair Removal Device

	Model(s): D-1128, D-1103, D-1119, D-1129, D-1130
510(k) Number	K192432
Product Code	OHT
Regulation Number	21 CFR 878.4810
Regulation Class	II

(5) Description/ Design of device:

The IPL HAIR REMOVAL HANDSET 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 a Xenon Quartz Lamp Tube to emit light and a 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 emitting.

The IPL HAIR REMOVAL HANDSET includes only one model IPL-666.

(6) Indications for use:

IPL HAIR REMOVAL HANDSET 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 HANDSET (Enclosure and flash window)	Plastic, metal	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	Predicate device	Reference device	Remark
Trade name	IPL HAIR REMOVAL HANDSET Model: IPL-666	IPL Salon Hair Reduction System, Model: F60001	IPL Home Use Hair Removal Device Model(s): D-1128,	/

			D-1103, D-1119, D-1129, D-1130	
510 (k) number	Applying	K181568	K192432	/
Manufacturer	Shenzhen Junbobeauty Technology Co., Ltd.	Medical Device Branch of Zhangzhou Easepal Industrial Co., Ltd.	Shenzhen Bosidin Technology Co.,Ltd.	/
Regulation number	21CFR 878.4810	21CFR 878.4810	21CFR 878.4810	Same
Product code	OHT	OHT	OHT	Same
Class	II	II	II	Same
Indications for use/ Intended use	IPL HAIR REMOVAL HANDSET is an over-the-counter device intended for removal of unwanted body and/or facial hair.	The IPL Salon Hair Reduction System (Model: F60001) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. It 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 re-growing when measured at 6. 9. and 12 months after the completion of a treatment regimen.	IPL Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair.	Same
Prescription or OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick Skin Phototypes I-V	Unknown	Fitzpatrick Skin Phototypes I-V	Same
Treatment area	Used on facial hair below the chin line, arms, legs, underarms, bikini line.	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.	Similar

Device design				
Power source	An external power supply	Supplied by external adapter	Supplied by external power adapter	Same
Power supply	100~240V AC Input 12V3A DC Output	100-240 V AC; 50/60 Hz	Input: 100-240V 50/60Hz 1.0-0.5A Output: DC12V 3A	Different **Note 1**
Product compositions	IPL Hair Removal Handset and power adapter	Device includes a treatment window head, a facial adaptor and battery charger/ AC cord.	IPL host, lamp cartridge and power adapter	Similar
Structure design	Handheld	Handheld	Handheld	Same
Dimension	124*83*48.5mm	143 x69.5 x 43mm (H*W*D)	218 x 144 x 60mm	Different **Note 2**
Weight	186g	650g	355g	Different **Note 2**
Sterilization	Not required	Not required	Not required	Same
Output specification				
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Quartz Tube	Xenon Arc Flashlamp	Xenon lamp	Similar **Note 3**
Wavelength range (nm)	470nm ~1100nm	475nm~1200nm	Regular window: 510 ~ 1100nm Filter window: 600 ~ 1100nm	Similar **Note 3**
Energy density (J/cm^2)	Max 2.49J/cm^2	Max 5J/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)	Similar **Note 3**
Spot size (Size of treatment window) (cm^2)	3cm^2	1.72 cm^2 or 3.02 cm^2	Regular window: 4.5cm^2, 2.0cm^2, 3.0cm^2 Filter window: 2.5cm^2	Same
Pulse duration	11.5-15ms	11-12ms	7.5-14ms	Similar **Note 3**
Pulsing control	Finger switch	Finger switch	Finger switch	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Number of output channels	One channel	One channel	One channel	Same
Output	5 levels	5 levels	5 levels	Same

intensity level				
Skin sensor	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 Control?	Yes	Yes	Yes	Same
Additional features				
Skin-contacting components	Plastic enclosure and treatment window	IPL Lamp output window	Plastic enclosure and treatment window	Same
Materials of skin-contacting components	Plastic, metal	ABS	ABS, PC, Aluminium alloy	Different **Note 4**
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.	Same
Electrical safety	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC60601-2-57	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57	Similar
Photobiological safety	IEC62471	Unknown	IEC62471	Same

Comparison in details:

Note 1:

The power adapter has been tested along with the subject device for electrical safety, so this difference will not raise any safety/ effectiveness problems.

Note 2:

Although the appearance, weight and dimensions are different between the subject and predicate device, these differences are insignificant and do not raise any safety/ effectiveness problems.

Note 3:

The energy medium are both Xenon lamp, although they are a little different, the output specification such as wavelength range, energy density, pulse duration are close to the predicate's device range, these parameters of the subject device can be basically covered by the predicate devices' range, they are very similar. So this difference will not raise any safety/ effectiveness problems.

Note 4:

Although the "Materials of skin-contacting components" of the subject device and predicate device are not exactly the same, the skin-contacting components of the subject device has been tested and satisfied the standard requirements of ISO 10993-1. So this difference will not raise any safety/ effectiveness problems.

(9) Non-clinical studies and tests performed:

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

- ANSI AAMI ES 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"

(10) Conclusion

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device IPL HAIR REMOVAL HANDSET is as safe, as effective, and performs as well as the legally marketed predicate device, IPL Salon Hair Reduction System.