March 31, 2023

Shenzhen Yangyi Technology., Ltd
% Bing Huang
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: K230021
Trade/Device Name: IPL Hair Removal Device, Model(s): AP10, AP20, AP30, AP32
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: January 4, 2023
Received: January 4, 2023

Dear Bing Huang:

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

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)*
K230021

Device Name
IPL Hair Removal Device, Model(s): AP10, AP20, AP30, AP32

Indications for Use *(Describe)*
IPL Hair Removal Device 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 Yangyi Technology Co., Ltd.

Address: Third Floor South, NO. 201, Building A8, Hua Fa Industrial Area, Fuyuan 1st Road, ZhanCheng Community，Fuhai Street, Bao'an District, Shenzhen, City

Contact person: Wang Jie

Phone number: +86 17837655793

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Email: 971679079@qq.com

Date of summary prepared: 2023-3-27

(2) Proprietary name of the device

Trade name/model: IPL Hair Removal Device, Model(s): AP10, AP20, AP30, AP32

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

(3) Predicate and reference device

- **Predicate 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

- **Reference device**

Sponsor	Shenzhen Junbobeauty Technology Co., Ltd
Device Name and Model	IPL HAIR REMOVAL HANDSET， Model: IPL-666

510(k) Number	K220669
Product Code	OHT
Regulation Number	21 CFR 878.4810
Regulation Class	II

(4) Description/ Design of device:

The IPL Hair Removal Device 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 Device includes: AP10, AP20, AP30, AP32 four models. Their intended use, performance, structure design and operation, are essential the same for the device models, with main differences being product appearance, display contents, physical product dimension, treatment area (spot size), output energy and power supply.

(5) Indications for use:

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

(6) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
IPL Hair Removal Device (Enclosure and light-emitting window)	ABS+PC	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".

(7) Technological characteristics and substantial equivalence:

Item	Subject device	Predicate device	Reference device	Remark

Trade name	IPL Hair Removal Device Model(s): AP10, AP20, AP30, AP32	IPL Home Use Hair Removal Device Model: D-1128, D-1103, D-1119, D-1129,D-1130	IPL HAIR REMOVAL HANDSET Model: IPL-666	/
510 (k) number	Applying	K192432	K220669	/
Manufacturer	Shenzhen Yangyi Technology Co., Ltd.	Shenzhen Bosidin Technology Co., Ltd.	Shenzhen Junbobeauty 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 Device 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.	IPL HAIR REMOVAL HANDSET 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	Fitzpatrick Skin Phototypes I-V	Fitzpatrick Skin Phototypes I-V	Same
Treatment area	Used on facial hair below the chin line, arms, legs, underarms, bikini line.	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.	Used on facial hair below the chin line, arms, legs, underarms, bikini line.	Similar
Device design				
Power source	An external power supply	Supplied by external adapter	An external power supply	Same
Power supply	Input: 100~240V AC Output: AP10: 24V3A DC; AP20, AP30, AP20: 12V4A DC	Input: 100-240V 50/60Hz 1.0-0.5A Output: DC12V 3A	100~240V AC Input 12V3A DC Output	Different **Note 1**
Product compositions	IPL host and power adapter	IPL host, lamp cartridge and power adapter	IPL Hair Removal Handset and power adapter	Similar
Structure	Handheld	Handheld	Handheld	Same

design				
Dimension	AP10: 201*184*80mm AP20: 209*161*78mm AP30: 166*62*40mm AP32: 167*63*41mm	D-1128: 218*114*60mm D-1129: 207*137*63mm D-1103: 207*137*63mm D-1119: 198*141*83mm D-1130:212*141*64 mm	124*83*48.5mm	Different **Note 2**
Weight	AP10: 451g AP20: 421g AP30: 320g AP32:320g	D-1128: 355g D-1129:340g D-1103:365g D-1119:370g D-1130:340g	186g	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 Arc Flashlamp	Xenon Arc Flashlamp	Xenon Quartz Tube	Same
Wavelength range (nm)	530nm ~1100nm	Regular window: 510 ~ 1100nm Filter window: 600 ~ 1100nm	470nm~1100nm	Similar **Note 3**
Energy density (J/cm^2)	Max 4.3J/cm²	2.0~4.0J/cm² (applicable for model D-1128, D-1119, D-1129, D-1130) 2.5~4.5J/cm² (applicable for model D-1103)	Max 2.49 J/cm²	Similar **Note 3**
Spot size (Size of treatment window) (cm^2)	3.3 cm², 3.96 cm²,3.63 cm²	Regular window: 4.5cm^2, 2.0cm^2, 3.0cm^2 Filter window: 2.5cm^2	3 cm²	Similar **Note 4**
Pulse duration	8.8~13.2ms	7.5~14ms	11.5~15ms	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	5	5	Similar

intensity level	(applicable for model AP10, AP30, AP32) 9(applicable for model AP20)			**Note 5**
Skin sensor	Sensor fixed in host and can be moved to treatment part	Sensor fixed in device and can be moved to treatment part	Sensor fixed in handset and can be moved to treatment part	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Same
Additional features				
Skin-contacting components	Plastic enclosure and light-emitting window	Plastic enclosure and treatment window	Plastic enclosure and treatment window	Same
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	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-57	IEC60601-1-2 IEC60601-1 IEC60601-1-11 IEC60601-2-83	Same
Photobiological safety	IEC62471	IEC62471	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, the output specification such as wavelength range, energy density, pulse duration are close to the predicate and reference device's range, these parameters of the subject device can be basically covered by the predicate and reference devices' range, they are very similar. So this difference will not raise any safety/effectiveness problems.

Note 4:

Although there are differences between subject device models spot sizes compared to the predicate device, the energy density and other light output characteristics are sufficiently similar so that the treatment window size differences do not raise safety/effectiveness concerns when the device is used properly.

Note 5:

The model AP20 has nine different output levels, but the energy density range of this subject device mode is similar to the predicate device range.

(8) Non-clinical studies and tests performed:

Non-clinical testings have been conducted to verify that the IPL Hair Removal Device 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 conforms to the following performance 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 for conformance to the following performance 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"

(9) Conclusion

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