August 29, 2024

Shenzhen Junmei Technology Co., Ltd.
% Youshan Gong
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K241881
Trade/Device Name: IPL Hair Removal Device (JM-843, JM-865, JM-638)
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 21, 2024
Received: June 28, 2024

Dear Youshan Gong:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2024.08.29 14:10:22 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241881

Device Name
IPL Hair Removal Device (JM-843, JM-865, JM-638)

Indications for Use *(Describe)*
The 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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K241881 510(k) Summary

"510(k) Summary" as required by 21 CFR Part 807.92.

Date Prepared: 2024-8-28

I. Submitter

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II. Device

Name of Device: IPL Hair Removal Device
Model(s): JM-843,JM-865,JM-638
Common or Usual Name: Light Based Over-The-Counter Hair Removal
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHT
Regulation Number: 21 CFR 878.4810

III. Predicate Device and Reference Device

➤ Predicate Device

Manufacturer	Predicate Device	510(k) Number
Shenzhen Beauty EveryMoment intelligent electric Co.,Ltd.	IPL Home Use Hair Removal Device	K221001

➤ **Reference Device 1**

Manufacturer	Reference Device	510(k) Number
Shenzhen Jianchao Intelligent Technology Co., Ltd.	Hair Removal Device	K232575

➤ **Reference Device 2**

Manufacturer	Reference Device	510(k) Number
Shenzhen BSX Technology Electronics Co., Ltd.	IPL Hair Removal Device	K230097

IV. Device Description

IPL Hair Removal Device, is an over-the-counter, home-use device for unwanted hair reduction by using Intense Pulsed Light (IPL), and it has been designed 3 models with the same IPL technology for hair removal, which is model JM-843,JM-865,JM-638. The device 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.

IPL Hair Removal Device is a Pulsed Light system which emits intense pulsed light (IPL) at a wavelength ranging from 530-1200nm and 500-1200nm. The device works on the principles of selective photothermolysis. That is, causing thermal damage to target chromophores by using light of appropriate wavelength in pulses that exceeds the chromophores' thermal relaxation time but sparing normal skin by limiting the pulse width below the thermal relaxation time for skin.

V. Indications for Use

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

VI. Materials

Model	Contacted Component Name	Materials
JM-843,JM-865,JM-638	Host of machine (including air outlet, treatment window, air inlet, buttons)	ABS, PC

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

VII. Comparison of Technological Characteristics With the Predicate Device

The IPL Hair Removal Device has the same intended use as the predicate. The technological characteristics such as wavelength, energy density, spot size and pulse duration, are similar to the predicate device and reference devices. Any minor differences between the subject device and the listed predicate device and reference devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device and reference devices for its intended use.

IPL Hair Removal Device is compared with the following Predicate Devices in terms of intended use, design, material, specifications and performance:

Comparison Elements	Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Remark
Model	JM-843, JM-865	JM-638	D-1189	R2815-G Pro, R2815-G	BSXT101	
510(k) Number	Pending		K221001	K232575	K230097	/
Trade name	IPL Hair Removal Device		IPL Home Use Hair Removal Device	Hair Removal Device	IPL Hair Removal Device	/
Manufacturer	SHENZHEN JUNMEI TECHNOLOGY CO., LTD.		Shenzhen Beauty EveryMoment intelligent electric Co.,Ltd.	Shenzhen Jianchao Intelligent Technology Co., Ltd.	Shenzhen BSX Technology Electronics Co., Ltd.	/
Regulation number	21 CFR 878.4810		21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT		OHT	OHT	OHT	Same
Device classification	Class II		Class II	Class II	Class II	Same
Indication for use/ Intended use	The 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.	Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair.	The IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/ or facial hair.	Same

Comparison Elements	Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Remark
Prescription or OTC	OTC		OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick skin types I-V		Fitzpatrick skin types I-V	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Same
Power supply	100-240V, 50/60Hz	100-240V, 50/60Hz	100-240V, 50/60Hz	100-240V, 50/60Hz	100-240V, 50/60Hz	Same
Dimension	194*91*55 mm	132*80*52 mm	197*60*38 mm	194*117*45mm	190 x 70 x 45 mm	Different **Note 1**
Sterilization	Not required	Not required	Not required	Not required	Not required	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp	Xenon Arc lamp	Xenon Arc lamp	Xenon Arc lamp	Xenon Arc lamp	Same
Wavelength range	530nm~1200nm	500nm~1200nm	550~1100nm	530~1200nm	470~1200nm	Same
Energy density	1.94 ~ 5.45 J/cm^2	1.20 ~ 4.00 J/cm^2	2.0~4.3J/cm^2 (±20%)	Max 5.2 J/cm^2	Max 5.0 J/cm^2	Similar **Note 2**
Output energy	8J ~ 15J, ±20% BODY: 8/10/11.5/13/15 J FACE: 8.5/9.5/10.5/11.5/12.5 J PRIVATE PARTS: 8.5/10/11/12.5/13.5 J ALL: 8.5 J	4.5J ~ 10J, ±20% Mode 1: 4.5/6/7.5/8.5/10 J	Body: 6/7.5/9/10.5/12 Face: 6/7.5/9/10.5/12 Bikini: 6/7.5/9/10.5/12 Underarm: 7.5/8.6/9.7/10.8/12 (±20%)	5-14.5J	Pure mode: 5~10J (±20%) Armpit mode: 6~10J (±20%) Body mode: 6.5~11J (±20%) Bikini mode: 8~12.5J	Similar **Note 2**

Comparison Elements	Subject Device		Predicate Device	Reference Device 1	Reference Device 2	Remark
					(±20%)	
Spot size	3.3cm^2± 0.25cm^2	3.0cm^2± 0.25cm^2	3.0cm^2	3.4cm^2± 0.5cm^2	3.0cm^2± 0.5cm^2	Similar Note 3
Pulse duration	10.2±1ms	9.0±1 ms	5~12ms+/-20%	8.5±2.5ms	4-10ms	Same
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Finger switch	Same
Output intensity level	1~5 levels	1~5 levels	1~5 levels	1~9 levels	1~5 levels	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Yes	Same
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	Same
Eye safety	IEC 62471	IEC 62471	IEC 62471	IEC 62471	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Same

Note 1:

Though the dimension is different from the predicate device and reference device, this difference is insignificant and do not raise any safety or effectiveness problems.

Note 2:
Though the energy density and the output energy of subject device is a little different from the predicate device and reference device, consider the error ±20%, the energy density and the output energy of subject device is similar to the predicate device and reference device, and they all comply with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Note 3:
There is minor difference in spot size between the subject device and the reference device. The spot size is related to energy density while the energy density of subject device and predicate device is the same as explained in Note 2, so this difference is not significant and will not raise any safety or effectiveness issue.

VIII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the subject device was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process", as recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5:2009, Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices –Part 10: Tests for skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices –Part 23: Tests for skin irritation

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, 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: 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

3) Eye Safety

- IEC 62471 Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with ***basic documentation level*** was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

5) Performance (bench) testing

Verification Report of Times of Flash: The valid IPL emission number (IPL shot counts) of the lamp tube is used to as the service life of the IPL Hair Removal Device. The service life as 300,000 times.

In order to verify and assure the performance, function and quality of the IPL Hair Removal Device, we have conducted the verification of output energy density, pulse duration time, valid times of flashes and Cold Compress Temperature.

IX. Conclusions

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 and reference device.