October 10, 2025

Foshan Jindi Electric Appliance Co., Ltd
℅ Tracy Che
Registration Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K252209
Trade/Device Name: IPL Home Use Hair Removal Device (JD-TM016, JD-TM023, JD-TM027, JD-TM028, JD-TM032)
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 15, 2025
Received: July 15, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.10.10 16:39:54 -04'00'

Tanisha Hithe
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252209

Please provide the device trade name(s).

IPL Home Use Hair Removal Device (JD-TM016, JD-TM023, JD-TM027, JD-TM028, JD-TM032)

Please provide your Indications for Use below.

IPL Home Use Hair Removal Device is an over-the-counter device intended for 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 regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

K252209

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

I. Contact details

Applicant name: Foshan Jindi Electric Appliance Co.,Ltd
Applicant address: No.13 Baiye Avenue, Xiqiao Science and Technology Industrial Park, Xiqiao Town, Nanhai District Foshan Guangdong China
Post code: 528211

Applicant contact: Zhaozhi Li
Position: Legal Person
Applicant contact phone: +86 18316578883
Applicant contact Email: renyigea@126.com

Prepared date: 2025-9-8

II. Device

Name of Device: IPL Home Use Hair Removal Device
Model(s): JD-TM016, JD-TM023, JD-TM027, JD-TM028, JD-TM032
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. Legally Marketed Predicate Device & Reference Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Ulike Smart Electronics Co., Ltd.	IPL Home Use Hair Removal Device	K230122	2023.04.10

Reference devices:

Manufacturer	Reference Device	510(k) Number	Approval Date
CyDen, Ltd.	iPulse Hair Removal System	K130315	2013.07.12
Shenzhen Ulike Smart Electronics Co.,Ltd.	Ice Cooling IPL Hair Removal Device	K241998	2024.12.13

IV. Device Description

IPL Home Use Hair Removal Device is an over-the-counter, home-use and personal device for hair reduction by using Intense Pulsed Light (IPL). It works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain.

IPL Home Use Hair Removal Device includes five models, JD-TM016, JD-TM023, JD-TM027, JD-TM028, JD-TM032. The five models adopt identical intended use, similar performance, operation and structure, with main differences in appearance, dimensions and weight, and light output parameters. Models JD-TM016, JD-TM023 are single pulse devices while models JD-TM027, JD-TM028 and JD-TM032 are double pulses devices. The device is only powered by the external power adapter. This device adopts sapphire flash outlet that is suitable for multiple hair removal areas.

The device is fitted with a skin sensor to detect appropriate skin contact, if the flash outlet of the device is not in full contact with the skin, the device cannot emit light pulses, and the IPL emission activation is by manual finger switch or auto light emission. The device has a cooling function that will be activated throughout the whole hair removal process to provide users with a more comfortable experience.

V. Indications for Use

IPL Home Use Hair Removal Device 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 regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

VI. Comparison of Technological Characteristics With the Predicate Device

The IPL Home Use Hair Removal Device has the same intended use, mode of action and similar operational characteristics as the predicate device. 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. Therefore, the IPL Home Use Hair Removal Device may be found substantially equivalent to its predicate device and reference devices.

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

Comparison Elements	**Subject Device**					**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Remark**
510(k) Number	K252209					K230122	K130315	K241998	/
Trade name	IPL Home Use Hair Removal Device					IPL Home Use Hair Removal Device	iPulse Hair Removal System	Ice Cooling IPL Hair Removal Device	/
Manufacturer	Foshan Jindi Electric Appliance Co.,Ltd					Shenzhen Ulike Smart Electronics Co.,Ltd.	CyDen, Ltd.	Shenzhen Ulike Smart Electronics Co.,Ltd.	/
Model	JD-TM016	JD-TM023	JD-TM027	JD-TM028	JD-TM032	UI04 SD, UI04 DG	/	/	
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	IPL Home Use Hair Removal Device is an over-the-counter device intended for 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 regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.					IPL Home Use Hair Removal Device 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 regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	The iPulse Hair Removal System is an over-the-counter device intended for the removal of unwanted hair.	Ice Cooling IPL Hair Removal Device with sapphire treatment window 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 regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	Same
Prescription or OTC	OTC					OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick skin types I-V					Fitzpatrick skin types I-V	Not publicly available	Fitzpatrick Skin Types I-V	Same
Treatment area	Limbs, armpits, back, chest, bikini and small areas (e.g.lip)					Large areas (e.g.arms, legs, chest) and small areas (e.g.lip)	Leg, arm, bikini, and underarm	Large areas (e.g.arms, legs, chest) and small areas (e.g.lip)	Same
Device design									
Energy source	Supplied by external adapter					Supplied by external adapter	Supplied by external adapter	Supplied by external adapter	Same
Power supply	100~240	100~240	100~240	100~240	100~240	100~240V, 50/60Hz	100~240V, 50/60Hz	100~240V, 50/60Hz	Same

Comparison Elements	Subject Device					Predicate Device	Reference Device 1	Reference Device 2	Remark
	V, 50/60Hz	V, 50/60Hz	V, 50/60Hz	V, 50/60Hz	V, 50/60Hz				
Dimension	180*100*47mm	179*60*36mm	182*60*35mm	180*100*48mm	170*62*37mm	60mm x 38mm x 170mm	Not publicly available	Not publicly available	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 Arc flashlamp	Xenon Arc flash lamp	Xenon Arc flash lamp	Same
Wavelength range	600±15~1200nm	550±15~1200nm	550±15~1200nm	600±15~1200nm	550±15~1200nm	560-1200nm	530-1100nm	550-1200mm	Similar
Energy density	2±0.4~5.5±1.1J/cm2	2±0.4~7±1.4J/cm2	2±0.4~8±1.6J/cm2	2±0.4~8±1.6J/cm2	2±0.4~7±1.4J/cm2	2.4-7.2J/cm²	7-10J/cm²	1.67~6.67J/cm²	Similar
Output energy	6±1.2~18±3.6J	6±1.2~20±4J	6±1.2~24±4.8J	6±1.2~24±4.8J	6±1.2~21±4.2J	9.9~19.8J	21~30J	6.5~26J	Similar
Spot size	3.3±0.2cm²	3.0±0.2cm²	3.0±0.2cm²	3.3±0.2cm²	3.0±0.2cm²	3.3cm²	3cm²	3.9cm²	Similar
Pulse duration	10ms±2ms	10ms±2ms	0.2±0.04ms-10ms±2ms	0.2±0.04ms-10ms±2ms	0.2±0.04ms-10ms±2ms	1.15-6.2ms	Variable - Single pulse 25milliseconds. Double Pulse 20ms on, 60 ms off.	0.88~3.20ms Multipulse	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
Output intensity level	5 levels~9 levels					5 levels	Not publicly available	1-10 Levels	Different
Software/ Firmware/ Microprocessor Control?	Yes					Yes	Yes	Yes	Same
Additional features									
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57					ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	Not publicly available	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	Same
Eye safety	IEC 62471					IEC 62471	Not publicly available	IEC 62471	Same

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device 1**	**Reference Device 2**	**Remark**
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Not publicly available	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same

VII. Non-Clinical Testing

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 IPL Home Use Hair Removal 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, Document Issued on September 4, 2020", as recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5 Third edition 2009-06-01, Biological Evaluation of Medical Devices - Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, as per the following standards:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: electromagnetic compatibility
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, 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 60601-2-57 Edition 1.0 2011-01, Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

3) Eye Safety

- IEC 62471 First edition 2006-07, 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) Usability

The product usability has been evaluated and verified according to the following FDA guidance

- Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016

VIII. Conclusions

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