April 6, 2025

Dongguan Boyuan Intelligent Technology Co.,Ltd
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co.Ltd
Room 1509, Jingting Building, Dongzhou Community,
Guangming Street, Guangming
Shenzhen, Guangdong 818000
China

Re: K250253
Trade/Device Name: IPL Hair Removal Device (KCA511/KCA516/KCA522)
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 26, 2025
Received: January 28, 2025

Dear Reanny Wang:

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: 2025.05.06 17:23:28 -04'00'

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

510(k) Number *(if known)*
K250253

Device Name
IPL Hair Removal Device (KCA511/KCA516/KCA522)

Indications for Use *(Describe)*
IPL 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K250253 - 510(k) Summary

I. SUBMITTER

Dongguan Boyuan Intelligent Technology Co.,Ltd.

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Contact Person: Li Jinlong

Date Prepared: Sep 29, 2024

II. DEVICE

Name of Device: IPL Hair Removal Device

Model(s): KCA511,KCA516,KCA522.

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

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Dongguan Boyuan Intelligent Technology Co.,Ltd.	IPL Hair Removal Device	K240282	April 3, 2024

This predicate has not been subject to a design-related recall.

Reference device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Ulike Smart Electronics Co.,Ltd.	IPL Hair Removal Device	K230122	April 10, 2023

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

IPL Hair Removal Device (Model: KCA511, KCA516,KCA522), 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.

The device is only powered by the external power adapter and its IPL emission activation is by finger switch. This product adopts irreplaceable treatment window and the spot size is 3.3cm^2 that is suitable for multiple hair removal areas. It contains a skin sensor to detect appropriate skin contact, if the device is not in full contact with the skin, the device cannot emit the treatment light pulses. Besides, the device has the cooling function that will be activated throughout the whole hair removal process to provide users with a more comfortable experience.

IPL Hair Removal Device, model: KCA511, KCA516 and KCA522 have the same indication for use, performance, structure design and operation, the only deference is their appearance size and weight.

IPL Hair Removal is used for removing excess facial hair and body hair and can also reduce hair regrowth. The products can be used on body parts such as underarm, bikini line, arms, facial hair below the chin line, back and legs.

It is designed so that the flash window requires full contact with the skin to work (flash),it will no works as long as the flash window does not contact the skin.

V. Indications for Use

IPL 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.

VI. Comparison of Technological Characteristics with the Predicate Device

The IPL Hair Removal Device has the same intended use, mode of action and similar operational characteristics as the predicate device and reference device. Any minor differences between the subject device and the listed predicate device and reference

device 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 device for its intended use. Therefore, the IPL Hair Removal Device may be found substantially equivalent to its predicate device and reference device. IPL Hair Removal Device is compared with the following Predicate Device and Reference Device in terms of intended use, design, specifications and performance:

Comparison Elements	Subject device	Predicate device	Reference device	Remark
510(k) Number	Pending	K240282	K230122	/
Trade name	IPL Hair Removal Device	IPL Hair Removal Device	IPL Hair Removal Device	/
Manufacturer	Dongguan Boyuan Intelligent Technology Co.,Ltd.	Dongguan Boyuan Intelligent Technology Co.,Ltd.	Shenzhen Ulike Smart Electronics Co.,Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT	OHT	OHT	Same
Device classification	Class II	Class II	Class II	Same
Indication for use/ Intended use	IPL 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	IPL 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	IPL 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	Same

	measured at 6, 9 and 12 months after the completion of a treatment regime.	measured at 6, 9 and 12 months after the completion of a treatment regime.	when measured at 6, 9 and 12 months after the completion of a treatment regime.	
Prescription or OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Same
Treatment area	Body parts such as underarm, bikini line, arms, facial hair below the chin line, back and legs.	Body parts such as underarm, bikini line, arms, facial hair below the chin line, back and legs.	large areas (e.g. arms, legs, chest) and small areas (e.g. lip)	Same
Device Design				
Source energy	Supplied by Power Adapter	Supplied by Power Adapter	Supplied by external adapter	
Power source	External power supply 1)Model:FX65U-240300C Input:100-240V AC 50/60Hz 2A Output:24.0V DC 3.0A 2)Model:DZ072CHL240300U Input:100-240V AC 50/60Hz 1.5A Output:24.0V DC 3.0A	External power supply； KCA450, KCA446, KCA504, KCA505, KCA506, KCA507, KCA508, KCA509: 1) Model: FX48U-120400C Input: 100-240V AC; 50/60Hz; 1.0A max Output: 12,0 V d.c.; 4,0 A 2) Model: DZ048CHL120400U Input: 100-240V AC; 50/60Hz; 1.5A max	External power supply:100-240 VAC, 50/60Hz	Different

		Output: 12,0 V d.c.; 4,0 A An external power supply； KCA501, KCA423, KCA448, KCA449, KCA502, KCA521: 1) Model: FX48U-120300C Input: 100-240V AC; 50/60Hz; 1.0A max Output: 12,0 V d.c.; 3,0 A 2) Model: DZ048CHL 120300U Input: 100-240V AC; 50/60Hz; 1.5A max Output: 12,0 V d.c.; 3,0 A		
Sterilization	Not required	Not required	Not required	Same
Dimensions	KCA511：178.2 *61.9 *36mm KCA516：177.3*65.4*37.4mm KCA522：177*70.2*43.1mm	KCA450: 170.8 *80.4 *41.3mm KCA446: 170.0 *80.5 *41.3mm KCA504: 172.1 *69.0 *37.8mm KCA505: 172.1 *69.0 *37.8mm KCA506: 171.0 *74.8 *41.9mm KCA507: 171.5 *74.5 *37.3mm	60mm x 38mm x 170mm	Different

		KCA508: 171.0 *74.8 *41.9mm KCA509: 171.5 *74.5 *37.3mm		
		KCA501: 163.5*79.1*42.8mm KCA423: 164.8*73.7*41.1mm KCA448: 162.0*76.4*42.2mm KCA449: 162.2*78.0*42.7mm KCA502: 164.2*75.8*38.3mm KCA521: 162.5*80.8*39.1mm		
Output Specification				
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Wavelength range	(610nm-1200nm) ±15nm	(600nm~1200nm) ±15nm	560-1200nm	Similar
Energy density	2.18~7.27J/cm^2	1.6~6J/cm^2	2.4~7.2J/cm2	Similar
Output energy	(9J~20J) ± 20%	(7.11J~17.41J) ± 20%	9.9~19.8J	Similar
Spot size	3.3cm²	3.5 cm²	3.3cm²	Same
Pulse duration	0.45ms±0.2ms (0.67-4.5)ms ±2ms	8~12ms	1.15-6.2ms	Different
Output intensity level	5	9	5	Same
Software/ Firmware/ Microprocess	Software control	Software control	Software control	Same

or Control？				
Additional Features				
Electrical safety	ANSI AAMI ES60601-1 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	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	Same
Eye safety	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	Same

VII. Performance Data

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

1) Biocompatibility testing

The biocompatibility evaluation for the IPL 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' " as recognized by FDA. The battery of testing included the following tests:

- ISO 10993-5:2009, Biological Evaluation of Medical Devices –Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices –Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-23: 2021, Biological evaluation of medical devices --Part 23: Tests for irritation

The IPL Hair Removal Device is considered tissue contacting for a duration of less than 24 hours.

2) Electrical Safety and EMC

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

- IEC 60601-1:2005/AMD1:2012/AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-11:2015/AMD1:2020 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 60601-2-83:2019/AMD1:2022 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

3) Eye Safety

- IEC 62471:2006 Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with moderate level of concern 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.

Summary

Based on the above performance as documented in this application, IPL Hair Removal Device was found to have a safety and effectiveness profile that is similar to the predicate device and reference device.

VIII. 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.