Novvember 14, 2025

Alovea Healthcare Co. Ltd.
% Moy Meng
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: K252618
Trade/Device Name: IPL Hair Removal Device (I6 S1, I6 D1, I6 M1)
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: August 19, 2025
Received: August 19, 2025

Dear Moy Meng:

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 Hithe

Digitally signed by Tanisha Hithe
Date: 2025.11.14 14:54:34 -05'00'

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

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)*
K252618

Device Name
IPL Hair Removal Device (I6 S1, I6 D1, I6 M1)

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.

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

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K252618 - 510(k) Summary

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

Date prepared: 2025-8-19

I. Submitter

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II. Device Information

Name of Device: IPL Hair Removal Device
Model(s): I6 S1, I6 D1, I6 M1
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
Regulation Number: 21 CRF 878.4810
Product Code: OHT
Review Panel: General & Plastic Surgery

III. Predicate Device and Reference Device

Predicate device 1:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
Shenzhen Yang Wo Electronic Co., Ltd	IPL Hair Removal Device Model: BE965A, BE965B, BE965C	K250171	March 19, 2025

Predicate device 2:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
Shenzhen Ulike Smart Electronics Co.,Ltd.	Ice Cooling IPL Hair Removal Device Model: UI20 DB, UI20 RE, UI20 GP, UI20 PW, UI20S DB, UI20S RE, UI20S PW, UI20S GP,UI20 WH, UI20 GR, UI20 BS, UI20 MP, UI20 BL, UI20 PN, UI20 BR, UI20WG, UI20S WH, UI20S GR, UI20S BS, UI20S MP	K241998	December 13, 2024

Reference device:

Manufacturer	Reference Device	510(k) Number	Cleared Date

Manufacturer	Reference Device	510(k) Number	Cleared Date
Shenzhen Ulike Smart Electronics Co.,Ltd.	Ice Cooling IPL Hair Removal Device Model(s): UI06S PR, UI06S PN, UI06S WH	K250194	March 26, 2025

IV. Device Description

IPL Hair Removal Device, is an over-the-counter, home-use device for unwanted hair removing by using Intense Pulsed Light (IPL), and it has been designed three models with the same IPL technology for hair removal, which is model I6 S1, I6 D1 and I6 M1. The device works below the skin's surface and does not involve any cutting or pulling, removing hair growth with minimal pain.

Model I6 S1 adopts single pulse technology, I6 D1 adopts dual pulse technology, and I6 M1 can switch between single pulse and dual pulse.

The device is only powered by the external power adapter and its IPL emission activation is by finger switch or auto flash mode.

The IPL Hair Removal Device has an irreplaceable light exit and it can cover an area of 3.3cm^2 that is suitable for multiple hair removal areas, such as limbs, armpits, upper lip, back, chest, bikini area.

The device contains a skin sensor to detect appropriate skin contact, if the flash window is not in full contact with the skin, the device cannot emit the treatment light pulses. Besides, the IPL Hair Removal Device has the sapphire ice cooling function, which will be activated throughout the whole hair removal process to cool down the treatment area's temperature and provide the user with a better using experience.

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

Component name	Material of Component	Body Contact Category	Contact Duration
Host of machine (including air outlet, treatment window, air inlet, buttons)	ABS	Surface-contacting device: Intact skin	Less than 24 hours
Sapphire cold head (within treatment window)	AL_2O_3	Surface-contacting device: Intact skin	Less than 24 hours

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 devices and reference device. Any minor differences between the subject device and the listed predicate devices 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 devices for its intended use. Therefore, the IPL Hair Removal Device may be found substantially equivalent to its predicate devices and reference devices.

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Reference Device	Remark
510(k) Number	Pending	K250171	K241998	K250194	/
Trade name	IPL Hair Removal Device	IPL Hair Removal Device	Ice Cooling IPL Hair Removal Device	Ice Cooling IPL Hair Removal Device	/
Model	I6 S1, I6 D1, I6 M1	BE965A, BE965B, BE965C	UI20 DB, UI20 RE, UI20 GP, UI20 PW, UI20S DB, UI20S RE, UI20S PW, UI20S GP,UI20 WH, UI20 GR, UI20 BS, UI20 MP, UI20 BL, UI20 PN, UI20 BR, UI20WG, UI20S WH, UI20S GR, UI20S BS, UI20S MP	UI06S PR, UI06S PN, UI06S WH	/
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.	The IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/ or facial 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	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	Same as predicate device 1

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Reference Device	Remark
510(k) Number	Pending	K250171	K241998	K250194	/
			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	OTC	Same
Power supply	100-240V～, 50Hz/60Hz	100-240V, 50/60Hz	100-240V~, 50/60Hz	100-240V～, 50Hz/60Hz	Same
Dimension	182x60x32mm	181*73*62mm	206.73mm*68.68mm*54.29mm	179.0*58.2*37.2mm	Different
Sterilization	Not required	Not required	Not required	Not required	Same
Light source	Intense Pulsed Light	Intense Pulsed Light (IPL)	Intense Pulsed Light (IPL)	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelength range	600-1200nm	600nm-1200nm	550-1200nm	550nm~1200nm	Same as predicate device 1
Energy density	I6 S1: 2.25J/cm^2~5.625J/cm^2 I6 D1: 2.75J/cm^2~6.56J/cm^2 I6 M1: (single pulse) 2.25J/cm^2~5.625J/cm^2, (dual pulse) 2.75J/cm^2~6.56J/cm^2	Max. 6.56J/cm^2 (range in 2.75～6.56J/cm^2)	1.67~6.67J/cm²	2.42-7.27J/cm^2	Similar
Spot size	3.3cm^2	3.2 cm²	3.9 cm²	3.3cm^2	Same as reference
Pulse duration	I6 S1 (single pulse): 0.7ms~5ms I6 D1 (dual pulse): 0.92ms~6.02ms I6 M1: (single pulse) 0.7ms~5ms/ (dual pulse): 0.92ms~6.02ms	0.82ms~5.32ms	0.88~3.20ms Multipulse	1.82-8.07ms multipulse	Similar
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Same

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Reference Device	Remark
510(k) Number	Pending	K250171	K241998	K250194	/
Output intensity level	Level 1~3	3 levels	1~10 levels	4 levels	Same as predicate device 1
Software/ Firmware/ Microprocessor Control?	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 60601-2-83	IEC 60601-1 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	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 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same

VIII. Performance Data

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

1) Biocompatibility Evaluation

The biocompatibility evaluation for the body-contacting components of 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'", Document Issued on September 4, 2020, as recommended by FDA.

- ISO 10993-5: 2009, Biological evaluation of medical devices – Par t 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 irritation

2) Electrical Safety and EMC

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

- IEC 60601-1-2: 2020, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility.
- IEC 60601-1: 2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-11: 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: 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 ***Basic Documentation*** 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.

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 devices.