March 26, 2025

Shenzhen Ulike Smart Electronics Co.,Ltd.
Blue Yang
Registration Director
810, Building 1, Xunmei Science and Technology Plaza, No. 8
Keyuan Road, Science Park Community, Yuehai Sub-District
Shenzhen, 518000
China

Re: K250194
Trade/Device Name: Ice Cooling IPL Hair Removal Device (UI06S PR, UI06S PN, UI06S WH)
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 23, 2025
Received: January 23, 2025

Dear Blue Yang:

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: 2025.03.26 16:53:55 -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

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.

Submission Number *(if known)*

K250194

Device Name

Ice Cooling IPL Hair Removal Device (UI06S PR, UI06S PN, UI06S WH)

Indications for Use *(Describe)*

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.

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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510(k) Summary of K250194

I. Submitter

Shenzhen Ulike Smart Electronics Co.,Ltd.
Address: 810, Building 1, Xunmei Science and Technology Plaza, No. 8 Keyuan Road, Science Park Community, Yuehai Sub-District, Nanshan District, Shenzhen 518000, Guangdong, P.R. China
Contact person: Blue Yang
Email: blue@ulike.com
The date the summary was prepared：3/19/2025

II. Device

Name of Device: Ice Cooling IPL Hair Removal Device
Model(s): UI06S PR, UI06S PN, UI06S WH
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 Devices

Legally Marketed Predicate Devices	Predicate Device 1	Predicate Device 2	Predicate Device 3
510(k) number	K242039	K230122	K221002
Trade Name	Ice Cooling IPL Hair Removal Device	IPL Hair Removal Device	IPL Hair Removal Device
Manufacturer	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen Ulike Smart Electronics Co., Ltd.

Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Product code	OHT	OHT	OHT
Device classification	Class II	Class II	Class II

IV. Device Description

Ice Cooling IPL Hair Removal Device is an over-the-counter, home-use and personal device for hair reduction by using Intense Pulsed Light (IPL). It is designed with a lamp that can emit continuously double or triple pulses per shot. It works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with nearly painless pain.

The device is only powered by the external power adapter and its IPL emission activation is by finger switch. This product adopts sapphire treatment window 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 ice cooling function that will be activated throughout the whole hair removal process to provide users with a more comfortable experience.

V. Indications for Use

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.

VI. Comparison of Technological Characteristics with the Predicate Device

The Ice Cooling IPL Hair Removal Device has the same intended use and similar operational characteristics as the predicate device. Any minor differences between the subject device and the listed predicate 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 for its intended use. Therefore, the IPL Hair Removal Device may be found substantially equivalent to its predicate device.

Ice Cooling IPL Hair Removal Device is compared with the following legally marketed devices in terms of intended use, design, specifications and performance:

Comparison Items	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3	Remark
510(k) number	/	K242039	K230122	K221002	/
Trade Name	Ice Cooling IPL Hair Removal Device	Ice Cooling IPL Hair Removal Device	IPL Hair Removal Device	IPL Hair Removal Device	/
Manufacturer	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen Ulike Smart 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	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,	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,	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 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 when	Same

	stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	stable reduction in the number of hairs regrowing when 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.	measured at 6, 9 and 12 months after the completion of a treatment regime.	
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
Treatment area	Large areas (e.g. arms, legs, chest) and small areas (e.g. lip)	Large areas (e.g. arms, legs, chest) and small areas (e.g. lip)	Large areas (e.g. arms, legs, chest) and small areas (e.g. lip)	Large areas (e.g. arms, legs, chest) and small areas (e.g. lip)	Same
Device design					
Source energy	Supplied by external adapter	Supplied by external adapter	Supplied by external adapter	Supplied by external adapter	Same
Power supply	100-240V~, 50/60Hz	100-240V~, 50/60Hz	100-240V~, 50/60Hz	100-240V~, 50/60Hz	Same
Dimension	179.0*58.2*37.2mm	206.73mm*68.68mm*54.29mm	60×38×170mm	60.5(W)x38(H)x169.7(L)mm	SE Note 1
Sterilization	Not required	Not required	Not required	Not required	Same
Output specification					
Light source	Intense Pulsed	Intense Pulsed	Intense Pulsed	Intense Pulsed Light	Same

	Light	Light	Light		
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelength range	550nm-1200nm	550-1200mm	560-1200mm	550-1200mm	Same
Energy density	2.42-7.27J/cm²	2.79J/cm2~6.41J/cm²	2.4-7.2J/cm²	3.03-5.3J/cm²	SE Note 2
Output energy	8-24J	10.9J~25J	9.9~19.8J	10.0~17.5J	SE Note 3
Spot size	3.3cm²	3.9cm²	3.3cm²	3.3cm²	Same
Pulse duration	1.82-8.07ms multipulse	0.93ms~3.50ms multipulse	1.15-6.2ms	7-10ms	SE Note 4
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	4 levels	1-10 Levels	5 Levels	5 Levels	SE Note 5
Software/Firmware /Microprocessor or Control?	Yes	Yes	Yes	Yes	Same
Additional features					
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	ANSI AAMI ES 60601-1 IEC 60601-1-2	ANSI AAMI ES 60601-1 IEC 60601-1-2	Same

	IEC 60601-2-57 IEC 60601-2-83	IEC 60601-2-57 IEC 60601-2-83	IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	
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 10993-5 ISO 10993-10	Same

Note 1:
The dimension belongs to basic characteristics. Although there is the dimension difference between subject device and the predicate devices, but it will not affect the function and intended use of the device, and they all comply with IEC 60601-1 requirements, so the difference will not raise safety and effectiveness issue.

Note 2:
Although there is a minor difference of the energy density between the subject device and predicate devices, but the energy density of subject device is very similar to the value of the predicate device 2, and they all comply with IEC 60601-2-57/IEC 60601-2-83 and IEC 62471 requirements, so such minor difference would not raise safety or effectiveness issue.

Note 3:
Although there is a minor difference of the output energy between the subject device and predicate device, but the output energy of subject device is within the range of the value of the predicate device 1, and they all comply with IEC 60601-2-57/IEC 60601-2-83 and IEC 62471 requirements, so such minor difference would not raise safety or effectiveness issue.

Note 4:
Although there is a minor difference of the pulse width between the subject device and predicate devices, it is within the pulse width value of the predicate device 3. Regarding the multipulse, the subject device operated on multipulse while the predicate device 2 also operated on multipulse. In addition, the subject device comply

with IEC 60601-2-83 and IEC 62471 requirement, so this difference will not raise any safety or effectiveness issue.

Note 5:
Though the subject device has 4 energy levels, which is different from the predicate devices, this difference is insignificant and do not raise any safety or effectiveness problems.

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 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", as recognized by FDA. The following testing was performed to, and passed, including:
> 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
> ISO 10993-5: 2009, Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
2) Electrical Safety and EMC
Electrical safety and EMC testing was performed to, and passed, as per the following standards:
> IEC 60601- 1:2005+A1:2012+A2:2020 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+A1:2020 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 60601-2-57:2011 Medical electrical equipment–Part 2-57: Particular requirements for the basic safety and essential performance of non-laser source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
> 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) Light Safety

> IEC 62471:2006 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 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 validated according to the following standard and FDA guidance.

> IEC 60601-1-6:2005+2012+2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

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

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