May 23, 2025

Shenzhen Ulike Smart Electronics Co., Ltd.
Blue Yang
Registration Director
810,Bldg 1,Xunmei Science and Tech Plaza, No.8 Keyuan Rd.
Science Park Community, Yuehai Sub-District, Nanshan Dist
Shenzhen,
China

Re: K250938
Trade/Device Name: Ice Cooling IPL Hair Removal Device (MI01 LP, MI01 CB, MI01 GR, MI01 PP, MI01 RM, MI01 WG, MI01 WH, MI01 BK;UI04S PP, UI04S BU, UI04S WH, UI04S PN)
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: March 28, 2025
Received: March 28, 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: 2025.05.23 11:26:03 -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.	K250938

Please provide the device trade name(s).

Ice Cooling IPL Hair Removal Device (MI01 LP, MI01 CB, MI01 GR, MI01 PP, MI01 RM, MI01 WG, MI01 WH, MI01 BK；UI04S PP, UI04S BU, UI04S WH, UI04S PN)

Please provide your Indications for Use below.

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.

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 of K250938

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：05/15/2024

II. Device

Name of Device: Ice Cooling IPL Hair Removal Device
Model(s): MI01 LP, MI01 CB, MI01 GR, MI01 PP, MI01 RM, MI01 WG, MI01 WH, MI01 BK；UI04S PP, UI04S BU, UI04S WH, UI04S PN
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 Devices

Predicate Device	Predicate Device 1	Predicate Device 2	Predicate Device 3
510(k) number	K242039	K130315	K240016

Trade Name	Ice Cooling IPL Hair Removal Device	iPulse Hair Removal System	IPL Hair Removal Device
Manufacturer	Shenzhen Ulike Smart Electronics Co., Ltd.	CyDen Ltd	Shenzhen Jianrong Biomedical 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 single pulse, double pulse or triple pulse 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 Devices have the same intended use and similar operational characteristics as the predicate devices. Any minor differences between the subject devices and the listed predicate devices do no raise any issues of safety or efficacy. Performance data supports that the devices are as safe and as effective as the predicate devices for its intended use. Therefore, the IPL Hair Removal Devices may be found substantially equivalent to its predicate devices.

Ice Cooling IPL Hair Removal Devices are 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	K250938	K242039	K130315	K240016	/
Trade Name	Ice Cooling IPL Hair Removal Device	Ice Cooling IPL Hair Removal Device	iPulse Hair Removal System	IPL Hair Removal Device	/
Manufacturer	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen Ulike Smart Electronics Co., Ltd.	CyDen Ltd	Shenzhen Jianrong Biomedical 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	Ice Cooling IPL Hair Removal Device with sapphire treatment window is indicated for the	The iPulse Hair Removal System is an Over-the-counter device intended for the removal of unwanted hair.	IPL Hair Removal Device is indicated for the removal of unwanted hair. The device is also indicated for the permanent	Same

	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.	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.		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.	
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	unknown	unknown	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)	leg, arm, bikini and underarm	unknown	Same
Device design					
Source energy	Supplied by external adapter	Supplied by external	Supplied by external adapter	Supplied by external adapter	Same

		adapter			
Power supply	100-240V~, 50/60Hz	100-240V~, 50/60Hz	100-240V~, 50/60Hz	100-240V~, 50/60Hz	Same
Dimension	MI01 series: 58.6(W)*35(H)*180.3(L)mm UI04S series: 179.4*58.7*36.4mm	206.73mm*68.68 mm*54.29mm	unknown	unknown	**SE** **Note 1**
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 Flashlamp	Xenon Arc Flashlamp	Same
Wavelength range	550-1200mm	550-1200mm	530-1100nm	550-1200nm	Same
Energy density	MI01 series: 1.8J/cm2~6.67J/cm2 Gentle mode：1.8J/cm² Face mode：2.8J/cm² Body mode：4.3J/cm² Bikini mode：6.67J/cm² UI04S series: 2.12~6.67J/cm² Soft Mode：2.12J/cm² Body Mode：3.52J/cm² Power Mode：4.55J/cm²	2.79J/cm2~6.41J/cm2	7-10J/cm²	1.2-4.3J/cm²	**SE** **Note 2**

	USHR Mode：6.67J/cm²				
Output energy	MI01 series:5.4~20J Gentle mode：5.4J Face mode：8.4J Body mode：12.9J Bikini mode：20J UI04S series:7-22J Soft Mode：7J Body Mode：11.6J Power Mode：15J USHR Mode：22J	10.9J~25J	21~30J	5.4~19.35J	**SE** **Note 3**
Spot size	MI01 series:3cm² UI04S series:3.3cm²	3.9cm²	3cm²	4.5cm²	Same
Pulse duration	MI01 series: 1.2~7ms Single pulse Triple pulse UI04S series: 1.47-7.52ms Double pulse Triple pulse	0.93ms~3.50ms Single pulse Double pulse Triple pulse	Variable - Single pulse 25milliseconds. to Double Pulse 20ms on, 60 ms off.	unknown	**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	unknown	unknown	**SE Note 5**
Software/Firmware/Microprocess or 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 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	unknown	IEC 60601-2-83	Same
Eye safety	IEC 62471	IEC 62471	unknown	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	unknown	unknown	Same

Note 1:
The dimension belongs to basic characteristics. Although there is the dimension difference between subject devices 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 devices and predicate devices, but the energy density of subject devices is within the range of the value of the predicate devices(the Maximum energy density of the subject devices is higher than the predicate device 1 but lower than the predicate device 2, the Minimum energy density of the subject devices is higher than the predicate device 3), 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 devices and predicate devices, but the output energy of subject devices is within the range of the value of the predicate devices(the Maximum output energy of the subject devices is lower than the predicate device 1 but higher than the predicate device 3, the Minimum output energy of the subject devices is higher than the predicate device 3), 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 devices and predicate devices, it is within the pulse width value of the predicate devices(the Maximum pulse width of the subject devices is lower than the predicate device 2 but higher than the predicate device 1, the Minimum pulse width of the subject devices is higher than the predicate device 1). In addition, the subject devices comply with IEC 60601-2-83 and IEC 62471 requirement, so this difference will not raise any safety or effectiveness issue.
Regarding the double pulse or triple pulse, the subject devices operated on multipulse while the predicate device 2 also operated on multipulse, and Temperature Test Report and Usability evaluation has been conducted to verify the users can use the device with multiple pulses safely and effectively, so such difference would not raise safety or effectiveness issue.

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

VII. Performance Data

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

Summary of performance 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 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 IPL Hair Removal Device is as safe, as effective, and performs as well as the legally marketed predicate device.