September 9, 2024

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

Re: K241205
Trade/Device Name: Y6S GR, Y6S GA,Y6S GT, Y6S JU, Y6S JM, Y6S MU, Y6S OG, Y6S CH,Y6S PN,Y6S NK, Y6S PG, Y6S TG, Y6S OE
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: April 30, 2024
Received: April 30, 2024

Dear Yang Blue:

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: 2024.09.09 22:59:19 -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.

510(k) Number *(if known)*
K241205

Device Name
Ice Cooling IPL Hair Removal Device (Y6S GR, Y6S GA,Y6S GT, Y6S JU, Y6S JM, Y6S, MU, Y6S OG, Y6S CH,Y6S PN,Y6S NK, Y6S PG, Y6S TG, Y6S OE)

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary of K241205

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：09/08/2024

II. Device

Name of Device: Ice Cooling IPL Hair Removal Device
Model(s): Y6S GR, Y6S GA,Y6S GT, Y6S JU, Y6S JM, Y6S MU, Y6S OG, Y6S CH,Y6S PN,Y6S NK, Y6S PG, Y6S TG, Y6S OE
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. Device Description

Ice Cooling IPL Hair Removal Device is an over-the-counter, home-use and single-person-use 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.

This product emits light pulses and is designed to be suitable for multiple hair removal areas (such as: lips, underarms, bikini lines, arms, legs, etc.). The device is only powered by the external power adapter and its IPL emission activation is by finger switch. The device 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. The device includes a cooling function to cool the skin during the hair removal process to provide users with a more comfortable experience.

IV.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.

V. Comparison of Technological Characteristics With the Predicate Devices

The Ice Cooling IPL Hair Removal Device has the same intended use and similar operational characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate devices do no raise new types of questions regarding safety and efficacy when the device is used for the indications for use stated above. 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.

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

Comparison Items	Subject Device	Predicate Device 1	Predicate Device 2
510(k) number	K241205	K221002	K240264
Trade Name	Ice Cooling IPL Hair Removal Device	IPL Hair Removal Device	Home use hair removal device
Manufacturer	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen Mlay Intelligent Technology 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
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	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	The Home use hair removal device is an over-the-counter device intended for removal of unwanted hair such as but not limited to small

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	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.	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.	areas such as underarm and facial hair below the chin line and large areas such as legs, in patients with Fitzpatrick Skin Phototypes I-V.
Prescription or OTC	OTC	OTC	OTC
Applicable skin	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Types I-V
Treatment area	Large areas (e.g. arms, legs, chest) and small areas (e.g. moustache)	Large areas (e.g. arms, legs, chest) and small areas (e.g. moustache)	small areas such as underarm and facial hair below the chin line and large areas such as legs
Source energy	Supplied by external adapter	Supplied by external adapter	Not known
Power supply	100-240V~, 50/60Hz	100-240V~, 50/60Hz	Not known
Dimension	114×89×45mm	60.5(W)x38(H)x16 9. 7(L)mm	Not known
Sterilization	Not required	Not required	Not required
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Wavelength range	550-1200nm	550-1200nm	510~1200nm
Energy density	1.45J/cm²~5J/cm²	3.03-5.3J/cm²	1.37~5.23J/cm²
Output energy	4.35J~15J	10.0~17.5J	Not known
Spot size	3.0cm²	3.3cm²	3.5cm²,3.9cm²
Pulse width	0.88~6.6ms	7-10ms	0.5~8.0ms
Pulsing control	Finger switch	Finger switch	Finger switch
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue
Output intensity level	3 Levels	5 Levels	Not known
Software/Firmware/	Yes	Yes	Yes

Microprocess or Control?			
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	ANSI AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	ANSI AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83
Eye safety	IEC 62471	IEC 62471	IEC 62471
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10

Note 1:
Although there is a minor difference of the energy density range between the subject device and predicate devices, the maximum energy density of subject device is within the range of the value of the predicate devices and the difference is not considered to raise concerns regarding safety or effectiveness .

Note 2:
There are minor differences in spot sizes between the subject device and the predicate devices. Given that the maximum energy density and pulse width range of the subject device is within the range of the applicable predicate, the differences in spot sizes are not considered to raise concerns regarding safety and effectiveness.

Note 3:
Although there are difference in the pulse duration range between the subject device and predicate devices, the maximum and minimum pulse duration of subject device is within the range of the value of the applicable predicate device. Given the subject device's energy density, treatment window size, and other parameters, the difference in pulse duration range is not considered to raise concerns regarding safety and effectiveness.

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 60601-2-83:2019 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 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: The proposed device uses technology that is similar to the predicate device. The technology and design do not raise new types of questions regarding safety and effectiveness for the proposed indications for use, and the performance testing supports that the device can be used safely and effectively for the proposed indications for use. The proposed device is considered to be substantially equivalent to the predicate devices