April 10, 2023

Shenzhen Ulike Smart Electronics Co., Ltd
% Riley Chen
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K230122
Trade/Device Name: IPL Hair Removal Device, Model(s): UI04 SD, UI04 DG
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 15, 2023
Received: January 17, 2023

Dear Riley Chen:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Colin K. Chen -S

for

Jianting Wang
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230122

Device Name
IPL Hair Removal Device
Model(s): UI04 SD, UI04 DG

Indications for Use *(Describe)*
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 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.

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510(k) Summary

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

I. Submitter

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II. Device

Name of Device: IPL Hair Removal Device
Model(s): UI04 SD, UI04 DG
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

Primary predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
CyDen Limited.	iPulse SmoothSkin Gold Hair Removal System	K160968	Apr.14, 2016

Predicate device:

Manufacturer	Reference Device	510(k) Number	Approval Date
Shen Zhen CosBeauty Co., Ltd	IPL Hair Removal Device Joy Version, CB-027	K173813	Sept. 07, 2018

Reference device:

Manufacturer	Reference Device	510(k) Number	Approval Date
Dongguan Define Beauty Electronic Technology Co. Ltd	IPL HAIR REMOVAL SG-8025	K212318	Jan.14, 2022

IV. Device Description

IPL Hair Removal Device (Model: UI04 SD, UI04 DG), 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: UI04 SD, UI04 DG have the same indication for use, performance, structure design and operation, the only deference is their enclosure color (UI04 SD is Star White and UI04 DG is Dark Green).

V. Indications for Use

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 measured at 6, 9 and 12 months after the completion of a treatment regime.

VI. Materials

Component name	Material of Component	Body Contact Category	Contact Duration
IPL Hair Removal Device (Enclosure and treatment window)	ABS, PC, Crystal application	Surface-contacting device: Intact skin	Less than 24 hours

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to "Biocompatibility Discussion".

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

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device**	**Reference Device**	**Remark**
510(k) Number	Pending	K160968	K173813	K212318	/
Trade name	IPL Hair Removal Device	iPulse SmoothSkin Gold Hair Removal System	IPL Hair Removal Device Joy Version, CB-027	IPL HAIR REMOVAL SG-8025	/
Manufacturer	Shenzhen Ulike Smart Electronics Co.,Ltd.	Cyden Limited.	Shen Zhen CosBeauty Co., Ltd	Dongguan Define Beauty Electronic Technology 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, GEX	OHT	OHT	Same
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	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 measured at 6, 9 and 12 months after the completion of a treatment regime.	The iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse Smoothskin Gold 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.	The IPL Hair Removal Device Joy Version 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. The device is used for adults with Fitzpatrick skin types I - IV.	The IPL Hair Removal (Model: SG-8025) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6. 9. and 12 months after the completion of a treatment regimen.	Same, only wording difference
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Applicable	Fitzpatrick Skin	Unknown	Fitzpatrick skin types I -	Unknown	Different

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Predicate Device**	**Reference Device**	**Remark**
skin	Types I-V		IV		
Treatment area	large areas (e.g. arms, legs, chest) and small areas (e.g. lip)	Unknown	Large areas (legs, arms, back and abdomen), face (upper lip, chin and sideburns)	Body and face	Similar
Device design					
Source energy	Supplied by external adapter	External Power supply	Supplied by external adapter	Supplied by external adapter	Same
Power supply	100~240V, 50/60Hz	110V or 230V, 50/60Hz	100-240 VAC, 50/60Hz	Unknown	Same
Dimension	60mm x 38mm x 170mm	Unknown	126*78*200mm	205*76*56mm (H*W*D)	Different
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 lamp	Same
Wavelength range	560-1200nm	510-1100nm	510-1200nm	530nm	Similar
Energy density	2.4-7.2J/cm^2	3-6J/cm^2	1.8~5.1J/cm^2	2.5J/cm^2 Max	Similar
Output energy	9.9~19.8J	9~18J	Body lamp cartridge: 11.77~22.21J 510-1200nm Facial lamp cartridge: 3.65~7.04J 512-1197nm Bikini lamp cartridge: 3.84~7.22J 511-1200nm	Level 1: 7.5J Level 2: 8.5J Level 3: 9.5J Level 4: 11J Level 5: 12J	Similar
Spot size	3.3cm^2	3cm^2 (3cm by 1cm)	Body: 4.2cm^2 Bikini and face: 2.0cm^2	3.0cm^2	Similar
Pulse duration	1.15-6.2ms	2ms to 10ms	9.2~11.2ms	1ms	Different
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	5	Unknown	5	5	Same

Comparison Elements	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	Remark
Software/ Firmware/ Microprocessor or Control?	Yes	Yes	Yes	Yes	Same
Additional features					
Electrical safety	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	Similar
Eye safety	IEC 62471	IEC 62471	Unknown	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

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 Issued on September 4, 2020", as recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5:2009, Biological Evaluation of Medical Devices –Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices –Par t 10: Tests for Irritation and Skin Sensitization

2) Electrical Safety and EMC

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

- ANSI AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 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 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 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 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 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.

5) Usability

The product usability has been evaluated and verified 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

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 devices.

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 device and reference devices.