November 19, 2025

Gu'an Yeolight Smart Electronics Co., Ltd
℅ Bing Huang
RA Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518082
China

Re: K253035
Trade/Device Name: IPL Hair Removal Device (SYL001AZ, SYL002AZ)
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: September 21, 2025
Received: September 22, 2025

Dear Bing Huang:

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: 2025.11.19 11:06:12 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253035

Device Name
IPL Hair Removal Device (SYL001AZ, SYL002AZ)

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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510(k) Summary
K253035

As required by 21 CFR Part 807.92.

Date: 2025-10-24

I. Submitter

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II. Device

Name of Device: IPL Hair Removal Device
Model(s): SYL001AZ,SYL002AZ
Common or Usual Name: Light Based Over-The-Counter Hair Removal
Classification 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 & Reference Device

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
Shenzhen Lescolton Electrical Appliance Co., Ltd.	IPL Hair Removal Device	K232499	October 11, 2023
Glan Electronics Co., Ltd.	IPL Hair Removal,(Model:OBT-02)	K213041	November 18, 2021

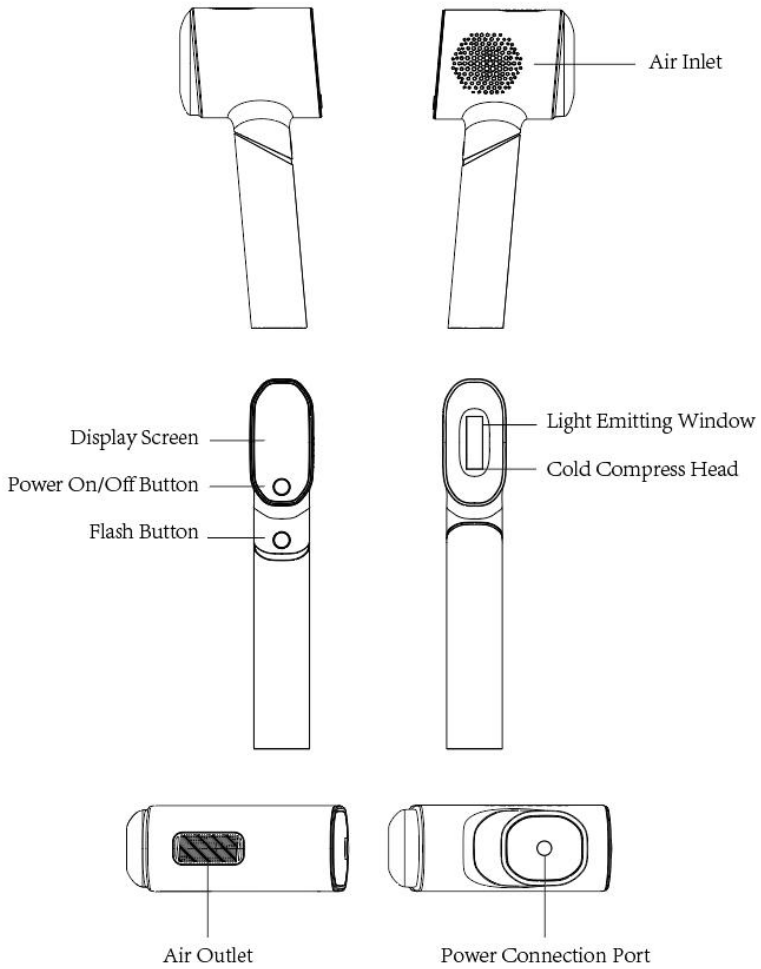
IV. Device Description

The IPL Hair Removal Device provides hair reduction using Intense Pulsed Light (IPL) technology, and it works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain.
The IPL Hair Removal Device is only powered by the external power adapter and its IPL emission activation is by finger switch. The device contains of main unit, power adapter and protective goggles.

The device contains a skin sensor to detect appropriate skin contact, if the light emitting 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 cooling function, which will be activated throughout the whole hair removal process to cool down the treatment area's temperature by the Sapphire and provide the user with a better using experience.

There are SYL001AZ and SYL002AZ two models in this application. Their work principle, function, intended use, structure, appearance and composition are the same, with the only difference in treatment level.

The IPL Hair Removal Device has the components shown as following illustration:



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. Comparison of Technological Characteristics With the Predicate Device

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

Comparison Elements	**Subject Device**		**Predicate Device 1**	**Predicate Device 2**	**Remark**
510(k) Number	Pending		K232499	K213041	/
Trade name	IPL Hair Removal Device		IPL Hair Removal Device	IPL Hair Removal	/
Model	SYL001AZ	SYL002AZ	LS-T106, LS-T107, LS-T108	OBT-02	/
Manufacturer	Gu'an Yeolight Smart Electronics Co.,Ltd		Shenzhen Lescolton Electrical Appliance Co., Ltd	Glan Electronics Co., Ltd.	/
Regulation number	21 CFR 878.4810		21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT		OHT	OHT	Same
Device classification	Class II		Class II	Class II	Same
Prescription or OTC	OTC		OTC	OTC	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.	The IPL Hair Removal Device OBT-02 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 re-growing when measured at 6, 9 and 12 months after the completion of a treatment regime. The device is used for adults.	Same
Applicable skin	Fitzpatrick skin types I-V		Fitzpatrick skin types I-V	Not publicly available	Same
Power supply	Out: AC 100V - 240V,50Hz/60Hz,1.5A Input: DC 24V, 2.5A		Not publicly available	AC Powered (100-240 V AC)	Same

Comparison Elements	**Subject Device**		**Predicate Device 1**	**Predicate Device 2**	**Remark**
Dimension	About 235mm × 105mm × 40mm		LS-T106: 202.3±0.8*38*56.2 mm LS-T107: 211.5*63.5*48.9 mm LS-T108: 177.5*67*40 mm	150*75*45 mm(H*W*D)	**Different** **Note 1**
Light source	Intense Pulsed Light		Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp		Xenon Arc lamp	Xenon Arc Flashlamp	Same
Wavelength range	510nm-1200nm		LS-T106: 610-1200nm LS-T107: 560-1200nm LS-T108: 470-1200nm	510nm~1100nm	**Similar** **Note 2**
Energy density	Level 1: 1.52J/cm² Level 2: 2.27J/cm² Level 3: 3.03J/cm² Level 4: 3.79J/cm² Level 5: 4.55J/cm²	Level 1: 1.52J/cm² Level 2: 3.03J/cm² Level 3: 4.55J/cm²	LS-T106: 2.0-4.87J/cm² LS-T107: 2.16-5.18J/cm² LS-T108: 2.0-5.62J/cm²	Level 1: 1.5 J/cm² Level 2: 1.9 J/cm² Level 3: 2.6 J/cm² Level 4: 3.7 J/cm² Level 5: 4.0 J/cm²	**Similar** **Note 2**
Output energy	Level 1: 5.0J Level 2: 7.5J Level 3: 10J Level 4: 12.5J Level 5: 15J	Level 1: 5J Level 2: 10J Level 3: 15J	LS-T106: 8/10/13J (±20%) LS-T107: 10/13/16J (±20%) LS-T108: 8/12/15J (±20%)	Level 1: 4.5 J Level 2: 5.7 J Level 3: 7.8 J Level 4: 11.1 J Level 5: 12 J	**Similar** **Note 2**
Spot size (Treatment area)	3.3 cm²		LS-T106: 3.2 cm² LS-T107: 3.7 cm² LS-T108: 3.2 cm²	3.0 cm²	**Same**
Pulse duration	1.1ms-8.25ms		LS-T106: 0.64-2.4ms LS-T107: 7.2-10.8ms LS-T108: 6.8-10.2ms	3 ms	**Similar** **Note 3**
Output intensity level	5 levels	3 levels	LS-T106: 3 levels LS-T107: 3 levels LS-T108: 3 levels	5 levels	Same
Software/ Firmware/ Microprocessor	Yes		Yes	Yes	Same

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Remark**
Control?				
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	Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57	Same
Eye safety	IEC 62471	IEC 62471	Not publicly available	Same
Biocompatibility	ISO 10993-5, ISO 10993-10, ISO 10993-23	ISO 10993-5 ISO 10993-10	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	Same

VII.Performance Data

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

1) Biocompatibility Safety

The materials of the patient-directly contacting components of the subject device is performed the biocompatibility evaluation 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. 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: 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 Safety

Electrical safety and Eye safety testing was performed to, and passed, the following standards:

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION, Medical Electrical Equipment –Part 1: 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.

Summary

Based on the above performance as documented in this application, the subject device was found to have a safety and effectiveness profile that is similar to the predicate devices.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design and performance, it can be concluded that the IPL Hair Removal Device is as safe, as effective, and performs as well as the legally marketed predicate devices.