December 29, 2025

Shenzhen Fansizhe Science And Technology Co., Ltd.
℅ Youshan Gong
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center
3101-90, Qianhai Rd.
Shenzhen, Guangdong 518052
China

Re: K253881
Trade/Device Name: Intense Pulsed Light (IPL) System (Models: T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T505KQ, T505KH, T505KF, SL-B505WM)
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: November 27, 2025
Received: December 4, 2025

Dear Youshan Gong:

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,

MARK MACIOS -S
Digitally signed by MARK MACIOS -S
Date: 2025.12.29 12:49:44 -05'00'

for 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)*
K253881

Device Name
Intense Pulsed Light (IPL) System (Models: T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T505KQ, T505KH, T505KF, SL-B505WM)

Indications for Use *(Describe)*
Intense Pulsed Light (IPL) System is an over-the-counter device intended for removal of unwanted body 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.

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K253881 510(k) Summary

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

Date Prepared: 2025-12-23

I. Submitter

Shenzhen Fansizhe Science And Technology Co., Ltd
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II. Device

Name of Device: Intense Pulsed Light (IPL) System (Models**:** T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T505KQ, T505KH, T505KF, SL-B505WM)
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 and Reference Device

➢ Predicate Device

Manufacturer	Predicate Device	510(k) Number
Shenzhen Fansizhe Science And Technology Co., Ltd	Intense Pulsed Light (IPL) System, Model: T033KQ, T033KD, T033KF T033MQ, T033MD, T033MF T055KQ, T055KD, T055KH	K251173

➢ Reference Device 1

Manufacturer	Reference Device	510(k) Number
Shenzhen Ulike Smart Electronics Co.,Ltd.	Ice Cooling IPL Hair Removal Device (UI20 DB, UI20 RE, UI20 GP, UI20 PW, UI20S DB, UI20S RE, UI20S PW, UI20S GP, UI20 WH, UI20 GR, UI20 BS, UI20 MP, UI20 BL, UI20 PN, UI20 BR, UI20WG, UI20S WH, UI20S GR, UI20S BS, UI20S MP)	K241998

IV. Device Description

Intense Pulsed Light (IPL) System (Models: T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T505KQ, T505KH, T505KF, SL-B505WM) are a small over-the-counter device for the removal of hair growth based on 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 power adapter and its IPL emission activation is by a switch or auto light emission.

Intense Pulsed Light (IPL) System, all models, contains a Xenon arc flashlamp, and a touch chip to detect appropriate skin contact. If the device is not properly applied to the treatment area (in full contact with the skin), the device cannot emit the treatment light pulses.

Based on the cooling technology, Intense Pulsed Light (IPL) System, models: T033KQ, T033KD, T033KF, T055KQ, T055KD, T055KH, T505KQ, T505KH, T505KF, SL-B505WM, has cooling care functions. When the cooling care mode is enabled, it can reduce the excessive heat generated on the skin by the photon irradiation and do cooling compresses during hair removal.

All models have single pulse, dual pulse and three pulse functions.

The Intense Pulsed Light (IPL) System includes main unit, an adaptor and goggles.

The device is intended to be used for adults aged over 18.

V. Indications for Use

Intense Pulsed Light (IPL) System is an over-the-counter device intended for removal of unwanted body hair.

VI. Materials

Model	Contacted Component Name	Materials
T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T505KQ, T505KH, T505KF, SL-B505WM	Host of machine (including air outlet, treatment window, air inlet, buttons)	ABS, PC

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

VII. Comparison of Technological Characteristics with the Predicate Device

The Intense Pulsed Light (IPL) System has the same intended use, mode of action and similar operational characteristics as the predicate device. Any minor differences between the subject device and the listed predicate devices do not 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 Intense Pulsed Light (IPL) System may be found substantially equivalent to its predicate device.

Intense Pulsed Light (IPL) System is compared with the following Predicate Devices in terms of intended use, design, material, specifications and performance:

Comparison Elements	**Subject Device**				**Predicate Device**	**Reference Device**	**Remark**
Model	**T033KQ, T033KD, T033KF**	**T033MQ, T033MD, T033MF**	**T055KQ, T055KD, T055KH**	**T505KQ, T505KH, T505KF, SL-B505WM**	**T033KQ, T033KD, T033KF** **T033MQ, T033MD, T033MF** **T055KQ, T055KD, T055KH**	**UI20 DB**	
510(k) Number	K253881				K251173	K241998	/
Trade name	Intense Pulsed Light (IPL) System				Intense Pulsed Light (IPL) System	Ice Cooling IPL Hair Removal Device	/
Manufacturer	Shenzhen Fansizhe Science And Technology Co., Ltd				Shenzhen Fansizhe Science And Technology Co., Ltd	Shenzhen Ulike Smart Electronics Co.,Ltd.	/
Regulation number	21 CFR 878.4810				21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT				OHT	OHT	Same

Comparison Elements	**Subject Device**				**Predicate Device**	**Reference Device**	**Remark**
Model	**T033KQ, T033KD, T033KF**	**T033MQ, T033MD, T033MF**	**T055KQ, T055KD, T055KH**	**T505KQ, T505KH, T505KF, SL-B505WM**	**T033KQ, T033KD, T033KF** **T033MQ, T033MD, T033MF** **T055KQ, T055KD, T055KH**	**UI20 DB**	
Device classification	Class II				Class II	Class II	Same
Indication for use/ Intended use	The Intense Pulsed Light (IPL) System is an over-the-counter device intended for the removal of unwanted body hair.				The Intense Pulsed Light (IPL) System is an over-the-counter device intended for the removal of unwanted body hair.	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	Same

Comparison Elements	**Subject Device**				**Predicate Device**	**Reference Device**	**Remark**
Model	**T033KQ, T033KD, T033KF**	**T033MQ, T033MD, T033MF**	**T055KQ, T055KD, T055KH**	**T505KQ, T505KH, T505KF, SL-B505WM**	**T033KQ, T033KD, T033KF** **T033MQ, T033MD, T033MF** **T055KQ, T055KD, T055KH**	**UI20 DB**	
						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	Same
Applicable skin	Fitzpatrick skin types I-IV				Fitzpatrick skin types I-IV	Fitzpatrick Skin Types I-V	Same
Sterilization	Not required				Not required	Not required	Same
Light source	Intense Pulsed Light				Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp				Xenon Arc lamp	Xenon Arc lamp	Same

Comparison Elements	**Subject Device**				**Predicate Device**	**Reference Device**	**Remark**
Model	**T033KQ, T033KD, T033KF**	**T033MQ, T033MD, T033MF**	**T055KQ, T055KD, T055KH**	**T505KQ, T505KH, T505KF, SL-B505WM**	**T033KQ, T033KD, T033KF** **T033MQ, T033MD, T033MF** **T055KQ, T055KD, T055KH**	**UI20 DB**	
Wavelength range	560 (±20nm)~1200nm	560 (±20nm)~1200nm	560 (±20nm)~1200nm	560 (±20nm)~1200nm	560 (±20nm)~1200nm	550nm~1200nm	Same
Max. Output energy (J)	26.5J	28J	25J	26.5J	T033KQ, T033KD, T033KF: 16.7J T033MQ, T033MD, T033MF: 17.7J T055KQ, T055KD, T055KH: 15.8J	26J	Similar
Max. Energy density (J/cm²)	8.03J/cm²	8.48J/cm²	8.33J/cm²	8.03J/cm²	T033KQ, T033KD, T033KF: 5.1J/cm²	6.67J/cm²	Similar

Comparison Elements	**Subject Device**				**Predicate Device**	**Reference Device**	**Remark**
Model	**T033KQ, T033KD, T033KF**	**T033MQ, T033MD, T033MF**	**T055KQ, T055KD, T055KH**	**T505KQ, T505KH, T505KF, SL-B505WM**	**T033KQ, T033KD, T033KF** **T033MQ, T033MD, T033MF** **T055KQ, T055KD, T055KH**	**UI20 DB**	
					T033MQ, T033MD, T033MF: 5.4J/cm² T055KQ, T055KD, T055KH: 5.3J/cm²		
Pulse width of single pulse	0.4-12 ms	0.4-12 ms	0.4-12 ms	0.4-12 ms	0.4-12 ms	0.88-3.20 ms	Similar
Spot size	3.3cm²	3.3cm²	3.0cm²	3.3cm²	T033KQ, T033KD, T033KF: 3.3cm² T033MQ, T033MD,	3.9cm²	Same

Comparison Elements	**Subject Device**				**Predicate Device**	**Reference Device**	**Remark**
Model	**T033KQ, T033KD, T033KF**	**T033MQ, T033MD, T033MF**	**T055KQ, T055KD, T055KH**	**T505KQ, T505KH, T505KF, SL-B505WM**	**T033KQ, T033KD, T033KF** **T033MQ, T033MD, T033MF** **T055KQ, T055KD, T055KH**	**UI20 DB**	
					T033MF: 3.3cm² T055KQ, T055KD, T055KH: 3.0cm²		
Output intensity level	1~5 levels	1~5 levels	1~5 levels	1~5 levels	1~5 levels	1~10 levels	Same
Pulsing control	Finger switch				Finger switch	Finger switch	Same
Software/ Firmware/ Microprocessor Control?	Yes				Yes	Yes	Same
Operating environment	Temperature: 5-26℃ Relative humidity: 20-90%,				Temperature: 5-30℃ Relative	Temperature: 5-30℃ Relative humidity: 5-	Same

Comparison Elements	**Subject Device**				**Predicate Device**	**Reference Device**	**Remark**
Model	**T033KQ, T033KD, T033KF**	**T033MQ, T033MD, T033MF**	**T055KQ, T055KD, T055KH**	**T505KQ, T505KH, T505KF, SL-B505WM**	**T033KQ, T033KD, T033KF** **T033MQ, T033MD, T033MF** **T055KQ, T055KD, T055KH**	**UI20 DB**	
	without condensation Atmospheric Pressure: 70 kPa to 106 kPa				humidity: 20-90%, without condensation Atmospheric Pressure: 70 kPa to 106 kPa	90%, Atmospheric Pressure: 80 kPa to 106 kPa	
Storage and transportation environment	Temperature: -20 -55 ℃ Relative humidity: 5-95%, without condensation Atmospheric Pressure:70				Temperature: -20 -55 ℃ Relative humidity: 5-95%,	Temperature: -10 -55 ℃ Relative humidity: 5-90%, Atmospheric	Same

Comparison Elements	**Subject Device**				**Predicate Device**	**Reference Device**	**Remark**
Model	**T033KQ, T033KD, T033KF**	**T033MQ, T033MD, T033MF**	**T055KQ, T055KD, T055KH**	**T505KQ, T505KH, T505KF, SL-B505WM**	**T033KQ, T033KD, T033KF** **T033MQ, T033MD, T033MF** **T055KQ, T055KD, T055KH**	**UI20 DB**	
	kPa to 106 kPa				without condensation Atmospheric Pressure:70 kPa to 106 kPa	Pressure:50 kPa to 106 kPa	
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	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	Same
Eye safety	IEC 62471				IEC 62471	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23				ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	Same

VIII. Performance Data

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

1) Biocompatibility Testing

- The tissue-contacting materials of subject device are identical to the predicate device K251173. Furthermore, the material of Surface-contacting components of all models are Acrylonitrile-butadienestyrene plastic (ABS) and Polycarbonate (PC), which outlined in Section B of Attachment G in Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" released by the FDA on September 8, 2023. Thus, no biocompatibility test data were provided for this submission.

2) Electrical Safety and EMC

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

- IEC 60601-1: 2005+ AMD1: 2012+ AMD2: 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+AMD1: 2020 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: 2019+AMD1: 2022 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

3) Performance Testing

- Performance verification testing on energy output, fluence, and pulse duration

4) Eye Safety

- IEC 62471: 2006 Photobiological safety of lamps and lamp systems

5) Software Verification and Validation

Software documentation consistent with ***Basic Documentation Level*** was submitted in this 510(k) as recommended by FDA Guidance "Content of Premarket Submissions for Device Software Functions (2023)". 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.

IX. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device Intense Pulsed Light (IPL) System is as safe, as effective, and performs as well as the legally marketed predicate device.