



July 14, 2025

Shenzhen Fansizhe Science and Technology Co., Ltd.
% Youshan Gong
RA Specialist
Feiyong Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K251173

Trade/Device Name: Intense Pulsed Light (IPL) System (T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T002AQ, T002AD, T002AF, T002BQ, T002BD, T002BF, T050KQ, T050KD, T050KF)

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: April 16, 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,

TANISHA
L. HITHE -S

Digitally signed by
TANISHA L. HITHE -S
Date: 2025.07.14
14:48:12 -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

510(k) Number (if known)

K251173

Device Name

Intense Pulsed Light (IPL) System (Model(s): T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T002AQ, T002AD, T002AF, T002BQ, T002BD, T002BF, T050KQ, T050KD, T050KF)

Indications for Use (Describe)

The Intense Pulsed Light (IPL) System is an over-the-counter device intended for the 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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K251173 510(k) Summary

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

Date Prepared: 2025-7-10

I. Submitter

Shenzhen Fansizhe Science And Technology Co., Ltd

2nd, 3rd And 4th floors, No.11, Henggangxia Industrial Zone, Xiangshan Community, Xinqiao Street, Bao'an District, Shenzhen Guangdong, CN 518125

Post code: 518125

Endang Cheng

Title: General Manager

Tel: +86 18617061709

E-mail: ChengEndang1001@163.com

II. Device

Name of Device: Intense Pulsed Light (IPL) System

Model(s): T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T002AQ, T002AD, T002AF, T002BQ, T002BD, T002BF, T050KQ, T050KD, T050KF

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**

<u>Manufacturer</u>	<u>Predicate Device</u>	<u>510(k) Number</u>
Shenzhen Fansizhe Science And Technology Co., Ltd	Intense Pulsed Light (IPL) System, Model: T013C, T015C, T015K	K221569

➤ **Reference Device 1**

<u>Manufacturer</u>	<u>Reference Device</u>	<u>510(k) Number</u>
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

➤ **Reference Device 2**

<u>Manufacturer</u>	<u>Reference Device</u>	<u>510(k) Number</u>
Shenzhen IONKA Medical Technology Co., Ltd.	Hand-held IPL device (IPL Home Use Hair Removal Device), Model: FZ-608, FZ-608G, FZ-100, FZ-200	K230739

IV. Device Description

Intense Pulsed Light (IPL) System, models: T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T002AQ, T002AD, T002AF, T002BQ, T002BD, T002BF, T050KQ, T050KD, T050KF, are a small over-the-counter device for the permanent reduction 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.

Intense Pulsed Light (IPL) System, models: T002AQ, T002AD, T002AF, contains a Xenon arc flashlamp, a touch chip to detect appropriate skin contact, and a skin color sensor to detect the skin color. In "Skin Color Recognition mode", the device's skin sensor automatically detects skin tone for your protection. If your skin tone is not in tone table suitable for treatment, the device must not be used. You need to identify your skin tone before treatment according to skin tone table, and confirm whether the product is applicable to you after the skin color sensor detects a skin tone.

Based on the cooling technology, Intense Pulsed Light (IPL) System, models: T033KQ, T033KD, T033KF, T055KQ, T055KD, T055KH, T050KQ, T050KD, T050KF, 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.

Based on the dual pulse technology, Intense Pulsed Light (IPL) System, models: T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T050KQ, T050KD, T050KF, has single pulse and dual 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, T002AQ,	Host of machine (including air outlet, treatment window, air inlet, buttons)	ABS, PC

T002AD, T002AF, T002BQ, T002BD, T002BF, T050KQ, T050KD, T050KF		
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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:

<u>Comparison Elements</u>	<u>Subject Device</u>						<u>Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Remark</u>
Model	T033KQ T033KD T033KF	T033MQ T033MD T033MF	T055KQ T055KD T055KH	T002AQ T002AD T002AF	T002BQ T002BD T002BF	T050KQ T050KD T050KF	T013C	UI20 DB	FZ-608 FZ-608G FZ-100 FZ-200	
510(k) Number	K251173						K221569	K241998	K230739	/
Trade name	Intense Pulsed Light (IPL) System (T033KQ, T033KD, T033KF, T033MQ, T033MD, T033MF, T055KQ, T055KD, T055KH, T002AQ, T002AD, T002AF, T002BQ, T002BD, T002BF, T050KQ, T050KD,						Intense Pulsed Light (IPL) System (Model:	Ice Cooling IPL Hair Removal Device (UI20 DB,	Hand-held IPL device (IPL Home Use Hair	/

<u>Comparison Elements</u>	<u>Subject Device</u>						<u>Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Remark</u>
Model	T033KQ T033KD T033KF	T033MQ T033MD T033MF	T055KQ T055KD T055KH	T002AQ T002AD T002AF	T002BQ T002BD T002BF	T050KQ T050KD T050KF	T013C	UI20 DB	FZ-608 FZ-608G FZ-100 FZ-200	
	T050KF)						T013C, T015C, T015K)	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)	Removal Device), Model: FZ-608, FZ-608G, FZ-100, FZ-200	
Manufacturer	Shenzhen Fansizhe Science And Technology Co., Ltd						Shenzhen Fansizhe Science And Technology Co., Ltd	Shenzhen Ulike Smart Electronics Co., Ltd.	Shenzhen IONKA Medical 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	OHT	OHT	Same
Device classification	Class II						Class II	Class II	Class II	Same
Indication for use/	The Intense Pulsed Light (IPL) System is an over-the-counter device						The Intense	Ice Cooling IPL	IPL Home Use	Same

<u>Comparison Elements</u>	<u>Subject Device</u>						<u>Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Remark</u>	
Model	T033KQ T033KD T033KF	T033MQ T033MD T033MF	T055KQ T055KD T055KH	T002AQ T002AD T002AF	T002BQ T002BD T002BF	T050KQ T050KD T050KF	T013C	UI20 DB	FZ-608 FZ-608G FZ-100 FZ-200		
Intended use	intended for the removal of unwanted body hair.						Pulsed Light (IPL) System is an over-the-counter device intended for the removal of unwanted body hair.	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.	Hand-held IPL 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.		
Prescription or OTC	OTC						OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick skin types I-IV						Fitzpatrick skin	Fitzpatrick Skin	Fitzpatrick Skin	Same	

<u>Comparison Elements</u>	<u>Subject Device</u>						<u>Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Remark</u>
Model	T033KQ T033KD T033KF	T033MQ T033MD T033MF	T055KQ T055KD T055KH	T002AQ T002AD T002AF	T002BQ T002BD T002BF	T050KQ T050KD T050KF	T013C	UI20 DB	FZ-608 FZ-608G FZ-100 FZ-200	
							types I-IV	Types I-V	Types I-V	
Sterilization	Not required						Not required	Not required	Supplied by external adapter	Same
Light source	Intense Pulsed Light						Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp						Xenon Arc lamp	Xenon Arc lamp	Xenon Arc lamp	Same
Wavelength range	560 (±20nm) ~1200nm	560 (±20nm) ~1200nm	560 (±20nm) ~1200nm	560 (±20nm) ~1200nm	560 (±20nm)~ 1200nm	560 (±20nm)~ ~1200nm	510~1200nm	550nm~1200nm	510nm~1200nm	Similar
Max. Output energy (J)	16.7J	17.7J	15.8J	16.6J	16.6J	17.2J	16.1J	26J	10J	Similar
Max. Energy density (J/cm ²)	5.1J/cm ²	5.4J/cm ²	5.3J/cm ²	4.2J/cm ²	4.2J/cm ²	5.2J/cm ²	4.03J/cm ²	6.67J/cm ²	5.43J/cm ²	Similar
Spot size	3.3cm ²	3.3cm ²	3.0cm ²	4.0cm ²	4.0cm ²	3.3cm ²	4cm ²	3.9cm ²	3.0cm ²	Similar
Pulse duration	0.4~12m s	0.4~12m s	0.4~12m s	0.4~12m s	0.4~12ms	0.4~12ms	4~12ms	0.88~3.20ms	0.5~0.8 ms	Similar
Output intensity level	1~5 levels	1~5 levels	1~5 levels	1~5 levels	1~5 levels	1~3 levels	1~5 levels	1~10 levels	1~9 levels	Same
Pulsing control	Finger switch						Finger switch	Finger switch	Finger switch	Same
Software/ Firmware/ Microprocessor	Yes						Yes	Yes	Yes	Same

<u>Comparison Elements</u>	<u>Subject Device</u>						<u>Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Remark</u>
Model	T033KQ T033KD T033KF	T033MQ T033MD T033MF	T055KQ T055KD T055KH	T002AQ T002AD T002AF	T002BQ T002BD T002BF	T050KQ T050KD T050KF	T013C	UI20 DB	FZ-608 FZ-608G FZ-100 FZ-200	
Control?										
Operating environment	Temperature: 5-26°C Relative humidity: 20-90%, without condensation Atmospheric Pressure: 70 kPa to 106 kPa						Temperature: 5-30°C Relative humidity: 20-90%, without condensation Atmospheric Pressure: 70 kPa to 106 kPa	Temperature: 5-30°C Relative humidity: 5-90%, Atmospheric Pressure: 80 kPa to 106 kPa	Not public	Same
Storage and transportation environment	Temperature: -20 -55 °C Relative humidity: 5-95%, without condensation Atmospheric Pressure:70 kPa to 106 kPa						Temperature: -20 -55 °C Relative humidity: 5-95%, without condensation Atmospheric	Temperature: -10 -55 °C Relative humidity: 5-90%, Atmospheric Pressure:50 kPa to 106 kPa	Not public	Same

<u>Comparison Elements</u>	<u>Subject Device</u>						<u>Predicate Device</u>	<u>Reference Device 1</u>	<u>Reference Device 2</u>	<u>Remark</u>
Model	T033KQ T033KD T033KF	T033MQ T033MD T033MF	T055KQ T055KD T055KH	T002AQ T002AD T002AF	T002BQ T002BD T002BF	T050KQ T050KD T050KF	T013C	UI20 DB	FZ-608 FZ-608G FZ-100 FZ-200	
							Pressure:70 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	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	Same
Eye safety	IEC 62471						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	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 subject 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”, as recognized by FDA. The following testing was performed to, and passed, including:

- ISO 10993-5:2009, Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity

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- 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 skin irritation

2) Electrical Safety and EMC

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

- IEC 60601-1 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: 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 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.

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 and reference device.