June 24, 2024

Qiaocheng Li (Dongguan) Medical Instruments Co., LTD
% Riley Chen
RA Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center
No. 3101-90, Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K241120
Trade/Device Name: Intense pulsed light therapy apparatus (FDA01, FDA02, FDA03, FDA04S, FDA05S, FDA06, FDA06S, FDA07, FDA07S, FDA08, FDA09S, FDA10S)
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 22, 2024
Received: April 23, 2024

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 (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.

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: 2024.06.24 15:29:23 -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.

Submission Number *(if known)*

K241120

Device Name

Intense pulsed light therapy apparatus (FDA01, FDA02, FDA03, FDA04S, FDA05S, FDA06, FDA06S, FDA07, FDA07S, FDA08, FDA09S, FDA10S)

Indications for Use *(Describe)*

Intense pulsed light therapy apparatus 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K241120

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

I. Submitter

Qiaocheng Li (Dongguan) Medical Instruments Co., LTD
Room 302, Building 5, No.6, Lianhu Baoyuan Road, Tangxia Town, Dongguan City, Guangdong Province, China
Post code: 523712

Huang Quanhua
Title: Quality supervisor
Tel.: +86-18681107912
Email: 1s4_5ogp59ash7@dingtalk.com
Date: 2024.05.27

II. Device

Name of Device: Intense pulsed light therapy apparatus
Model(s): FDA01, FDA02, FDA03, FDA04S, FDA05S, FDA06, FDA06S, FDA07, FDA07S, FDA08, FDA09S, FDA10S
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 & Reference Device

Predicate devices:

Manufacturer	Predicate Device	510(k) Number	Cleared Date
Zhuzhou Goldenhot Medical Technology Co., Ltd.	Intense pulsed light device, Model(s): DE01A-B, DE01A-G, DE01B-B, DE01BG, DE01C-B, DE01C-G, DE02A-B, DE02A-G, DE02B-B, DE02B-G, DE02C-B, DE02C-G.	K231613	Jul. 31, 2023
Shenzhen Fansizhe Science And Technology Co., Ltd	Intense Pulsed Light (IPL) System, model T013C, T015C, T015K	K221569	Jun. 30, 2022

Reference device:

Manufacturer	Reference Device	510(k) Number	Cleared Date
Glan Electronics Co., Ltd.	IPL Hair Removal Device, model OBT-02	K213041	Nov. 18, 2021

IV. Device Description

Intense pulsed light therapy apparatus is an over-the-counter, home-use, light based device for unwanted hair reduction by using Intense Pulsed Light (IPL) technology. The device works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain.

The device includes 12 models (Model: FDA01, FDA02, FDA03, FDA04S, FDA05S, FDA06, FDA06S, FDA07, FDA07S, FDA08, FDA09S, FDA10S), the model name with an "S" indicates that the model has a cooling function. The device is only powered by the external power adapter and its IPL emission activation is by a switch or auto light emission, and the device contains a skin sensor to detect appropriate skin contact, if the light exit is not in full contact with the skin, the device cannot emit the treatment light pulses.

V. Indications for Use

Intense pulsed light therapy apparatus is an over-the-counter device intended for removal of unwanted body and/or facial hair.

VI. Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Intense pulsed light therapy apparatus (light outlet, enclosure)	ABS+PC+POM	Surface-contacting device: Intact skin	Less than 24 hours

VII. Comparison of Technological Characteristics With the Predicate Device

Intense pulsed light therapy apparatus has the same intended use as the predicate devices. The technological characteristics such as wavelength, energy density, spot size and pulse duration, are similar to the predicate devices and reference device. Any minor differences between the subject device and the listed predicate devices 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.

Intense pulsed light therapy apparatus is compared with the following Predicate Devices in terms of intended use, design, specifications and performance:

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary predicate device**	**Reference device**	**Remark**
510(k) Number	K241120	K231613	K221569	K213041	/
Trade name	Intense pulsed light therapy apparatus	Intense pulsed light device	Intense Pulsed Light (IPL) System	IPL Hair Removal Device	/
Model	FDA01, FDA02, FDA03, FDA06, FDA07, FDA08 FDA04S, FDA05S, FDA06S, FDA07S, FDA09S, FDA10S	DE01A-B, DE01A-G, DE01B-B, DE01BG, DE01C-B, DE01C-G, DE02A-B, DE02A-G, DE02B-B, DE02B-G, DE02C-B, DE02C-G.	T013C, T015C, T015K	OBT-02	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT	OHT	OHT, ONF	OHT	Same
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	Intense pulsed light therapy apparatus is an over-the-counter device intended for removal of unwanted body and/or facial hair.	The Intense pulsed light device is an over-the-counter device, intended for removal of unwanted body and/or facial hair.	The Intense Pulsed Light (IPL) System is an over-the-counter device intended for the removal of unwanted body 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	Same

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary predicate device**	**Reference device**	**Remark**
				treatment regime. The device is used for adults.	
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Environment of Use	Home use	Home use	Home use	Home use	Same
Design	Hand-hold	Hand-hold	Hand-hold	Unknown	Same
Power source	An external power supply	An external power adapter	An external power adapter	Supplied by external adapter	Same
Power supply	Input: 100-240V~, 50/60Hz	Input: AC 100 ～ 240V , 50/60 Hz, 1.0A	Input: 100-240V ～ 50/60Hz，1.5A Max.	100-240 V AC	Similar
Sterilization	Not required	Not required	Unknown	Not required	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon lamp	Xenon Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelength range	510-1200nm (±15nm)	510nm~1200nm	510nm~1200nm	510-1100nm	Same
Energy density	FDA01, FDA02, FDA03, FDA04S, FDA06, FDA06S, FDA07, FDA07S, FDA08, FDA10S: 1.2~2.64J/cm² FDA05S, FDA09S: 1.3~3.5J/cm²	1.2~4.1 J/cm²	1.17~4.69J/cm² for T015C	1.5-4.0J/cm²	Similar
Spot size	3.0cm²	3.9 cm²	3.5cm² for T015C	3.0cm²	Similar
Pulse duration	3.5~4.5ms (±0.9ms)	Body mode: 7.0~9.0 (±2.0)ms Face mode: 8.0~10.0 (±2.0)ms Bikini mode: 9.0~11.0	4~12ms for T015C	3ms	Similar

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary predicate device**	**Reference device**	**Remark**
		(±2.0)ms			
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Same
Output intensity level	5 levels	5 levels	Unknown	5 Levels	Same
Delivery device	Direct illumination to tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct illumination to tissue	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Same
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	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57	Same
Eye safety	IEC 62471	IEC 62471	IEC 62471	Unknown	Same
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	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 Intense Pulsed Light Therapy Apparatus 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: 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

Electrical safety and EMC testing was performed to, and passed, as per 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 1-11: 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 60601-2-83 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 according to the following FDA guidance:

- Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016

Summary

Based on the above performance as documented in this application, the Intense Pulsed Light Therapy Apparatus was found to have a safety and effectiveness profile that is similar to the predicate devices.

IX. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.