November 6, 2024

Shenzhen Greatro Electronic Technology Co., Ltd
Lucy Yan
Regulatory Manager
East Side, 4/F Building A1, Xu'xing'da Industrial Park
Shiyan Sub-district, Bao'an District
Shenzhen, Guangdong 518108
China

Re: K242595
Trade/Device Name: Intense Pulse Light Therapeutic Apparatus (IPL-18 BF, IPL-18 FG)
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: July 18, 2024
Received: August 30, 2024

Dear Lucy Yan:

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,

Yan Fu -S

Digitally signed by Yan Fu -S
Date: 2024.11.06 23:57:14 -05'00'

for Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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)*
K242595

Device Name
Intense Pulse Light Therapeutic Apparatus (IPL-18 BF, IPL-18 FG)

Indications for Use *(Describe)*
Intense Pulse Light Therapeutic Apparatus 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.

510(k) Summary K242595

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1 Administrative Information

Submission Date	July. 15, 2024
Manufacturer information	Submitter's Name: Shenzhen Greatro Electronic Technology Co., Ltd Address: East Side, 4/F Building A1, Xu'xing'da Industrial Park, Shiyan Sub-district, Bao'an District, Shenzhen, China. 518108 Contact person: Xinhua Yue TEL: +86 139 2374 2027 E-Mail: janis@jrdmic.com
Submission Correspondent	Contact person: Ms Lucy.Yan E-Mail: lucy.yan@aivikon.com Company: Shenzhen Greatro Electronic Technology Co., Ltd Address: East Side, 4/F Building A1, Xu'xing'da Industrial Park, Shiyan Sub-district, Bao'an District, Shenzhen, China. 518108 Tel: +8613316972203

2 Device Information

Common name of the device	IPL Hair Removal Device
Trade name of the device	Intense Pulse Light Therapeutic Apparatus
Type/Model of the device	IPL-18 BF, IPL-18 FG
Classification information	Classification panel: General & Plastic Surgery Classification name: Laser surgical instrument for use in general and plastic surgery and in dermatology Regulation Number: 21 CFR 878.4810 Device Class: II Product Code: OHT
type of 510(k) submission	Traditional

3 Primary predicate Device Information and Reference predicate Device Information

Predicate Device: Intense Pulse Light Therapeutic Apparatus

Sponsor:	Shenzhen Greatro Electronic Technology Co., Ltd.
Device:	Intense Pulse Light Therapeutic Apparatus, Model(s): IPL-1 PRO, IPL-1, IPL-12, IPL-17
510(K) Number:	K232932
Product code:	OHT
Approval date:	December 4, 2023

Reference Device: IPL Hair Removal Device

Sponsor:	Shenzhen Ulike Smart Electronics Co., Ltd
Device:	IPL Hair Removal Device, Model(s): UI06 PN, UI06 PL, UI06 JL, UI06 BR, UI06 DB, UI06 PR, UI06 OG, UI06 RD
510(K) Number:	K223618
Product code:	OHT
Approval date:	February 28, 2023

4 Device Descriptions

The Intense Pulse Light Therapeutic Apparatus is a personal, light-based, hair reduction device intended to be sold over-the-counter directly to the end user. The device provides hair reduction using Intense Pulsed Light (IPL) technology, and it works below the skin's surface and does notinvolve any cutting or pulling, reducing hair growth with minimal pain.The Intense Pulse Light Therapeutic Apparatus is only powered by the external power adapter and its IPL emission activation is by finger switch. The device contains a Xenon lamp and its built-in skin sensor to detect appropriate skin contact. If the device is not properly and fully applied to thetreated skin, the device will not emit the light pulse.There are IPL-18 BF and IPL-18 FG two models in this application. Their work principle, intended use, structure, appearance, size, and composition are the same, with differences being product function are slight differences, but these parameters are within the predicate device and do not affect or change the intended use of the device.

5 Intended Use/ Indications for Use

Intense Pulse Light Therapeutic Apparatus is an over-the-counter device intended for removal of unwanted body hair.

6 SE Comparisons

The subject device Intense Pulse Light Therapeutic Apparatus 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 device do no 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 subject device may be found substantially equivalent to its predicate device.The subject device is compared with the following Predicate Devices in terms of intended use, design, specifications, and performance:

Table 1. Substantial Equivalence Comparison

Characteristics	Subject device	Predicate device (K232932)	Reference Device (K223618)	Remark
Device Name	Intense Pulse Light Therapeutic Apparatus	Intense Pulse Light Therapeutic Apparatus	IPL Hair Removal Device	NA
Device Model	IPL-18 BF, IPL-18 FG	IPL-1 PRO, IPL-1, IPL-12, IPL-17	UI06 PL, UI06 PN, UI06 JL, UI06 BR, UI06 DB, UI06 PR, UI06 OG, UI06 RD	NA
Manufacturer	Shenzhen Greatro Electronic Technology Co., Ltd	Shenzhen Greatro Electronic Technology Co., Ltd	Shenzhen Ulike Smart Electronics Co., Ltd	NA
Product code	OHT	OHT	OHT	NA
Classification	II	II	II	NA
Intended Use/ Indication for Use	Intense Pulse Light Therapeutic Apparatus is an over-the-counter device intended for removal of unwanted body hair.	Intense Pulse Light Therapeutic Apparatus is an over-the-counter device intended for removal of unwanted body hair.	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 at6, 9 and 12 months after the completion of a treatment regime.	SE
Prescription or OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick skin types I-V	Fitzpatrick skin types I-V	Fitzpatrick skin types I-V	Same
Dimension	IPL-18 BF: 154*79*46mm; IPL-18 FG: 154*79*46mm	IPL-1PRO:133.5*83*48mm IPL-1: 133.5*83*48mm IPL-12:134*83.5*48.5mm IPL-17: 140.5*78*45mm	58×34×179 mm (W x H x D)	Different Note 01
Weight	IPL-18 BF: 213g IPL-18 FG: 201g	IPL-1 PRO:200g IPL-1: 194g IPL-12: 183g IPL-17: 184g	/	
Power source	Supplied by external adapter	Supplied by external adapter	Supplied by external adapter	Same
Power supply	Input: AC100~240V50/60Hz Output: DC12V 3A	Input: AC100~240V50/60Hz Output: DC12V 3A	100~240V, 50/60Hz	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

Wavelength range	510~1200nm	510~1200nm	560-1200mm	Same
Energy density	IPL-18 BF: 1.28~4.80J/cm^2; IPL-18 FG: 1.52~5.89J/cm^2	Max. 4.92 J/cm²	3~6 J/cm²	Different Note 02
Output energy	Level 1：6.0±1.2J Level 2：7.5±1.5J Level 3：9.5±1.9J Level 4：11.0±2.2J Level 5：13.0±2.6J Error is ±20%	Level 1: 6.0J Level 2: 7.5J Level 3: 9.5J Level 4: 11.0J Level 5: 12.5J Error is ±20%	9.9~19.8J	
Output energy level	1 to 5 level	1 to 5 level	1 to 3 level	Same
Spot size	IPL-18 BF: (3.5±0.25) cm^2; IPL-18 FG: (2.9±0.25) cm^2	3.3(±0.25) cm^2	3.3cm²	Different Note 02
Pulse duration	10.0±3.0ms	5.84~9.24ms	1ms~7ms	Different Note 03
Pulsing control	Finger switch	Finger switch	Finger switch	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Availability of skin sensors (that used to identify the presence or absence of skin areas)	Presence	Presence	Presence	Same
Software/Firmware/Microprocess or Control?	Yes	Yes	Yes	Same
Skin-contacting components	Device enclosure and treatment panel	Device enclosure and light outlet panel	Enclosure and treatment window	Different Note 04
Materials of skin-contacting components	IPL-18 BF: PC+ABS plastic, POM, Glass, and Aluminum alloy; IPL-18 FG: PC+ABS plastic, POM, Glass	PC+ABS plastic, Glass	ABS, PC, Crystal application	Different Note 04
Materials statement	All user directly contacting materials are compliance with ISO10993-5, ISO10993-10 and ISO 10993-23 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
EMC safety statement	Comply with IEC60601-1-2 requirements	Comply with IEC60601-1-2 requirements	Comply with IEC60601-1-2 requirements	Same
Electrical safety statement	Comply with IEC60601-1, IEC60601-1-11, IEC60601-2-83 requirements	Comply with IEC60601-1, IEC60601-1-11, IEC60601-2-83 requirements	Comply with IEC60601-1, IEC60601-1-11, IEC 60601-2-83 requirements	Same
Photobiological	Comply with IEC62471	Comply with IEC62471	Comply with IEC62471	Same

statement	requirements.	requirements.	requirements.	
Environment for operation	Temperature: 5℃~30℃Humidity: ≤80%RH	Temperature: 5℃~30℃Humidity: ≤80%RH	/	SE
Environment for storage	Temperature: -10℃~60℃Humidity: 5%~90%	Temperature: -10℃~60℃Humidity: 5%~90%	/	SE

Note 01: The "Weight", "Dimension", is belonging to basic physical characteristics, although it is a little different from the predicate devices, it will not affect the main function and the intended use of the device. They all also comply with IEC60601-1 requirements. Besides, the subtle change of the physical characteristics will not affect the critical functions or normal use, and not raise any safety or effectiveness issues

Note 02: The max "Energy density" of the subject device is lower than the Reference device, so the subject device is substantially equivalent to the device. Although there is a minor difference in the spot size between the subject device and the predicate device, the spot size and output energy level which is related to energy density. The subject device complies with IEC60601-1 and IEC60601-2-83 and since the difference in energy density is not significant and be substantially equivalent, so this difference will not raise any safety or effectiveness issue.

Note03: The "Pulse duration" of the subject device is little different from the predicate device. But the subject device complies with IEC60601-1 and IEC60601-2-83; so this difference will not raise any safety or effectiveness issues.

Note04: Although the “skin-contact components” and the "Materials of skin-contacting components" of the subject device and predicate device are not exactly the same, the skin-contacting components of the subject device has been tested and satisfied the standard requirements of ISO 10993-1. So this difference will not raise any safety/effectiveness problems.

These different technological characteristics of the subject devices do not raise different questions of safety and effectiveness. Thus, the subject device is Substantially Equivalent (SE) to the predicate devices which is legally marketed in US.

7 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 and passed, including:

- ISO 10993-5:2009, Biological evaluation of medical devices –Part 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 skin irritation

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed 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.

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 device.

8 Conclusions

The subject device:

Intense Pulse Light Therapeutic Apparatus is respectively substantially equivalent to the predicate device (Intense Pulse Light Therapeutic Apparatus) manufactured by Shenzhen Greatro Electronic Technology Co. (K232932) and reference device (IPL Hair Removal Device) manufactured by Shenzhen Ulike Smart Electronics Co., Ltd (K223618).