July 31, 2023

Zhuzhou Goldenhot Medical Technology Co., Ltd.
% Candice Qui
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K231613
Trade/Device Name: Intense pulsed light device, Model(s): DE01A-B, DE01A-G, DE01B-B, DE01B-G, DE01C-B, DE01C-G, DE02A-B, DE02A-G, DE02B-B, DE02B-G, DE02C-B, DE02C-G.
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: June 1, 2023
Received: June 2, 2023

Dear Candice Qui:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K231613

Device Name
Intense pulsed light device
Model(s): DE01A-B, DE01A-G, DE01B-B, DE01B-G, DE01C-B, DE01C-G, DE02A-B, DE02A-G, DE02B-B, DE02B-G, DE02C-B, DE02C-G

Indications for Use *(Describe)*
The Intense pulsed light 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.

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510(k) Summary - K231613

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

I. Submitter

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II. Device

Name of Device: Intense pulsed light device
Model(s): DE01A-B, DE01A-G, DE01B-B, DE01B-G, DE01C-B, DE01C-G, DE02A-B, DE02A-G, DE02B-B, DE02B-G, DE02C-B, DE02C-G
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	Approval Date
Shenzhen Fansizhe Science And Technology Co., Ltd	Intense Pulsed Light (IPL) System (T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K)	K223928	March 28, 2023

Reference device:

Manufacturer	Reference Device	510(k) Number	Approval Date
Shenzhen Junbobeauty Technology Co., Ltd	IPL HAIR REMOVAL HANDSET (IPL-666)	K220669	May 16, 2022

IV. Device Description

The Intense pulsed light device is a personal, light-based, hair reduction device. The device provides hair reduction using IPL technology. Of which, the Device includes DE01A-B, DE01A-G, DE01B-B, DE01B-G, DE01C-B, DE01C-G, DE02A-B, DE02A-G, DE02B-B, DE02B-G, DE02C-B, DE02C-G twelve models. All have adopted the same structure design, consisting of Intense pulsed light device main body and power adapter two parts, and one non-removable lamp head (light-emitting treatment window) located in the main body which is the source of optical radiation, namely a Xenon flashlamp. Meanwhile, the device is powered from power adapter via an external power. The difference of all models is mainly product size, appearance, sapphire, skin color recognition function and enclosure color, DE01A series means without sapphire and skin color recognition function. DE01B series means with sapphire, but without skin color recognition function. DE01C series means with sapphire and skin color recognition function. DE02A series means without sapphire and skin color recognition function. DE02B series means with sapphire, but without skin color recognition function. DE02C series means with sapphire and skin color recognition function. Letter -B the enclosure color is blue, letter -G is green, which do not affect the intended use.

V. Indications for Use

The Intense pulsed light device 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 device (Enclosure)	ABS, PC, POM	Surface-contacting device: Intact skin	Less than 24 hours

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to Section 16 “Biocompatibility Discussion”.

VII. Comparison of Technological Characteristics With the Predicate Device

The Intense pulsed light device 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 and reference 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 and reference device for its intended use. Therefore, the Intense pulsed light device may be found substantially equivalent to its predicate device and reference device.

Intense pulsed light device is compared with the following Predicate Device and Reference Device in terms of intended use, design, material, specifications, and performance:

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device**	**Remark**
510(k) Number	Pending	K223928	K220669	/
Trade name	Intense pulsed light device Model: DE01A-B, DE01A-G, DE01B-B, DE01B-G, DE01C-B, DE01C-G, DE02A-B, DE02A-G, DE02B-B, DE02B-G, DE02C-B, DE02C-G	Intense Pulsed Light (IPL) System Model: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K	IPL HAIR REMOVAL HANDSET Model: IPL-666	/
Manufacturer	Zhuzhou Goldenhot Medical Technology Co.,Ltd	Shenzhen Fansizhe Science And Technology Co., Ltd	Shenzhen Junbobeauty Technology 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
Indication for use/ Intended use	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.	IPL HAIR REMOVAL HANDSET is an over-the-counter device intended for removal of unwanted body and/or facial hair.	Same
Prescription or OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick Skin Types I-V	Fitzpatrick Skin Phototypes I-V	Fitzpatrick skin types I - V	Same

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device**	**Remark**
Treatment area	Small areas such as bikini line. Large areas such as arms, legs.	Used on facial hair below the chin line, arms, legs, underarms, bikini line.	Used on facial hair below the chin line, arms, legs, underarms, bikini line.	Similar
Device design				
Power source	An external power supply	An external power supply	Supplied by external adapter	Same
Power supply	Input: AC 100 ~ 240V , 50/60 Hz, 1.0A Output: 24V⎓2.5A	Unknown	100-240V AC Input 12V3A DC Output	Different
Dimension	DE01A-B, DE01A-G: 218(W)x77(H)x97(L)mm DE01B-B, DE01B-G, DE01C-B, DE01C-G: 218(W)x77(H)x103(L)mm DE02A-B, DE02A-G: 178(W)x67(H)x150(L)mm DE02B-B, DE02B-G, DE02C-B, DE02C-G: 183(W)x67(H)x150(L)mm	116*217.8*42mm for T023K, T023A, T023B, T023C, T023D and T023E 73.2*81.1*202.2mm for T021K and T021A 182*78*151mm for T001A, T001B, T001M and T001N 211*138*60mm for T011C 90*44*225mm for T016K	124 x83 x 48.5mm	Different
Sterilization	Not required	Not required	Not required	Same
Output specification				
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Flashlamp	Xenon Arc Flashlamp	Xenon Quartz Tube	Similar
Wavelength range	510-1200nm	510-1200nm	470-1100 nm	Similar
Energy density	Body mode: 1.2 ~ 4.1 J/cm2	5.5J/cm2 for T023K,	1.3-2.49 J/cm²	Similar

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device**	**Remark**
	Face mode : 1.2 ~ 4.1 J/cm2 Bikini mode: 1.2 ~ 4.1 J/cm2	T023A, T023B, T023C, T023D and T023E, 4.8J/cm2 for T021K and T021A, 4.7J/cm2 for T001A, T001B, T001M and T001N, 5.75J/cm2 for T011C, 5.73J/cm2 for T016K		
Output energy	Body: 6.4-14.0 J Face: 5.6-11.9 J Bikini line: 5.7-12.8 J	6.5J ~ 16.6J for T023K, T023A, T023B, T023C, T023D and T023E 5.6J ~ 14.5J for T021K and T021A 7.3J ~ 18.6J for T001A, T001B, T001M and T001N 5.3 J ~ 20.7J for T011C 4.8J ~ 18.9J for T016K	Level 1: 3.92J Level 2: 4.72J Level 3: 5.62J Level 4: 6.49J Level 5: 7.48J	Similar
Spot size	3.9 cm^2	3.0cm^2 for T023K, T023A, T023B, T023C, T023D, T023E, T021K and T021A, 4.0cm^2 for T001A, T001B, T001M and T001N, 3.6cm^2 for T011C, 3.3cm^2 for T016K	3 cm^2	Similar
Pulse duration	Body mode: 7.0±2.0 ~ 9.0±2.0 ms Face mode: 8.0±2.0 ~ 10.0±2.0 ms	4 ~ 12ms	11.5-15 ms	Similar

Comparison Elements	**Subject Device**	**Predicate Device**	**Reference Device**	**Remark**
	Bikini mode: 9.0±2.0 ~ 11.0±2.0 ms			
Pulsing control	Finger switch	Finger switch	Finger switch	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Output intensity level	5 Levels	Unknown	5 Levels	Same
Software/ Firmware/ Microprocessor or Control?	Yes	Yes	Yes	Same
Additional features				
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-83	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC60601-2-83	IEC 60601-1, IEC 60601-1-2 IEC 60601-1-11, IEC60601-2-83, IEC 62471	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	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 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 to, 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 to, and passed, as per the following standards:

- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- ANSI AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- 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 and verified according to the following FDA guidance

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

IX. Conclusions

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