November 20, 2023

Shenzhen Jianchao Intelligent Technology Co., Ltd.
% Riley Chen
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: K232575
Trade/Device Name: Hair Removal Device, Model(s): R2815-G Pro, R2815-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: August 25, 2023
Received: August 25, 2023

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
2023.11.20 14:28:35 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232575

Device Name
Hair Removal Device
Model(s): R2815-G Pro, R2815-G

Indications for Use *(Describe)*
Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair 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 - K232575

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

I. Submitter

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II. Device

Name of Device: Hair Removal Device
Model(s): R2815-G Pro, R2815-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

Primary predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen Fansizhe Science and Technology Co., Ltd	Intense Pulsed Light (IPL) System, model: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K	K223928	Mar. 28, 2023

Secondary predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Zhuzhou Goldenhot Medical Technology Co., Ltd.	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.	K231613	Jul. 31, 2023

IV. Device Description

Hair Removal Device (Model: R2815-G Pro, R2815-G), is an over-the-counter, home-use and personal device for hair reduction 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 Hair Removal Device includes two models that are R2815-G Pro, R2815-G, and their indications for use, work principle, product structure and composition, electrical structure, performance and operation are basically the same, the only difference is that the R2815-G Pro is equipped with sapphire while R2815-G is not but with a metal treatment window surface.

The device is only powered by the external power adapter. The device is fitted with a skin sensor to detect appropriate skin contact, if the treatment window of the device is not in full contact with the skin, the device cannot emit light pulses, and the IPL emission activation is by finger switch.

V. Indications for Use

Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair and/or facial hair.

VI. Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Hair Removal Device (Enclosure and treatment window)	PC+ABS, Sapphire (Al_2O_3), Stainless steel 430	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 "Biocompatibility Discussion".

VII. Comparison of Technological Characteristics With the Predicate Device

The Hair Removal Device has the same intended use, mode of action and similar operational characteristics as the predicate devices. 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 for its intended use. Therefore, the Hair Removal Device may be found substantially equivalent to its predicate devices.
Hair Removal Device 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**	**Remark**
510(k) Number	Pending	K223928	K231613	/

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Remark**
Trade name	Hair Removal Device	Intense Pulsed Light (IPL) System	Intense pulsed light device	/
Model	R2815-G Pro, R2815-G	T016K	DE01A-B, DE01A-G, DE01B B, DE01B-G, DE01C-B, DE01C G, DE02A-B, DE02A-G, DE02B B, DE02B-G, DE02C-B, DE02C-G	/
Manufacturer	Shenzhen Jianchao Intelligent Technology Co., Ltd.	Shenzhen Fansizhe Science and Technology Co., Ltd	Zhuzhou Goldenhot Medical 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	Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair 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 Intense pulsed light device is an over-the-counter device, intended for removal of unwanted body and/or facial hair.	Same
Prescription or OTC	OTC	OTC	OTC	Same
Device design				
Source energy	An external power supply	An external power supply	An external power supply	Same
Power supply	100~240V, 50/60Hz	100~240V, 50/60Hz	AC 100 ～240V , 50/60 Hz	Same
Dimension (mm)	194*117*45mm	90*44*225mm for T016K	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	Different
Sterilization	Not required	Not required	Not required	Same
Output specification				
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same

Comparison Elements	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Remark**
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Flashlamp	Same
Wavelength range	530-1200nm	510~1200nm	510~1200nm	Similar
Energy density	Max. 5.2J/cm^2	Max. 5.73J/cm^2 for T016K	1.2~4.1J/cm^2	Similar
Output energy	5~14.5J	4.8~18.9J for T016K	Body: 6.4-14.0 J Face: 5.6-11.9 J Bikini line: 5.7-12.8 J	Similar
Spot size	3.4±0.25 cm^2	3.3 cm^2 for T016K	3.9 cm^2	Similar
Pulse duration	8.5±2.5ms	4~12ms	Body mode: 7~9 (±2.0) ms Face mode: 8~10 (±2.0) ms Bikini mode: 9~11 (±2.0) ms	Similar
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	9 levels	Unknown	5 levels	Different
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Same
Additional information				
Electrical safety	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 60601-2-83	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 biocompatibility evaluation for the body-contacting components of the 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 –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 Hair Removal Device 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.