October 17, 2024

Shenzhen Huaruibo Electric Appliances Co., Ltd
℅ Tracy Che
Registration Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K242197
Trade/Device Name: IPL Hair Removal Device (DH4, DH5, DH5 Plus, DH5 Max)
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 26, 2024
Received: July 26, 2024

Dear Tracy Che:

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: 2024.10.17 17:27:59 -04'00'

for

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.*

510(k) Number *(if known)*
K242197

Device Name
IPL Hair Removal Device (DH4, DH5, DH5 Plus, DH5 Max)

Indications for Use *(Describe)*
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 at 6, 9 and 12 months after the completion of a treatment regime.

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.***

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| 510(k) #: K242197 | 510(k) Summary | Prepared on: 2024-10-09 |
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## Contact Details

21 CFR 807.92(a)(1)

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|---|---|
| Applicant Name | Shenzhen Huaruibo Electric Appliances Co., Ltd |
| Applicant Address | 3rd Floor, Building A, Chajiaokan Industrial Zone, Sanhe Village, Huarong Community, Dalang Street, Longhua District Shenzhen Guangdong 518103 China |
| Applicant Contact Telephone | +86-13600412127 |
| Applicant Contact | Mr. Xinhua Luo |
| Applicant Contact Email | kobe@data-hero.cn |
| Correspondent Name | Feiying Drug & Medical Consulting Technical Service Group |
| Correspondent Address | Rm 2401 Zhenye International Business Center, No. 3101-90, Qianhai Road Shenzhen Guangdong 518052 China |
| Correspondent Contact Telephone | +86-18027206248 |
| Correspondent Contact | Ms. Tracy Che |
| Correspondent Contact Email | 1273487536@qq.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | IPL Hair Removal Device (DH4, DH5, DH5 Plus, DH5 Max) |
| Common Name | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| Classification Name | Light Based Over-The-Counter Hair Removal |
| Regulation Number | 878.4810 |
| Product Code(s) | OHT |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K173813 | IPL Hair Removal Device Joy Version | OHT |
| K232932 | Intense Pulse Light Therapeutic Apparatus | OHT |

## Device Description Summary

21 CFR 807.92(a)(4)

IPL Hair Removal Device is the fast professional IPL with 6 levels for DH4, 8 levels for DH5, DH5 Plus and DH5 Max, and offers a beauty experience in comfort of your own home as well as has been designed with unique features for simple, relaxed and effective hair removal.
IPL Hair Removal Devices of models: DH4, DH5, DH5 Plus and DH5 Max consist of IPL host and power adapter. The host is mainly composed of hair removal lamp, power/level button, skin sensor, thermovent (fan), flash button and DC socket.

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. Besides, the IPL Hair Removal Devices of models DH5 Plus and DH5 Max have the cooling function, which will be activated throughout the whole hair removal process to cool down the treatment area's temperature and provide the user with a better using experience.

## Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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 at 6, 9 and 12 months after the completion of a treatment regime.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device and predicate devices have the same indications for use.

## Technological Comparison 21 CFR 807.92(a)(6)

The technical characteristic of IPL Hair Removal Device (DH4, DH5, DH5 Plus, DH5 Max) are substantially equivalent to the predicate devices in the following aspects:
1. the same intended use, mode of action;
2. the same source energy and power supply: supplied by external adapter with 100-240V~, 50/60Hz;
3. the same light source: Intense Pulsed Light;
4. the same energy medium: Xenon Arc Flashlamp;
5. the same wavelength: 510-1200nm.

The difference between the subject device and the predicate devices mainly includes the following:
1. different spot size: the spot size DH4 is 3.0cm$^2$ and 3.3 cm$^2$ for DH5, DH5 Plus, DH5 Max, which is different from the primary predicate device K173813. The spot size is related to energy density and since the energy density of the subject device is within the range of the predicate devices, so this difference will not raise any safety or effectiveness issue.
2. different energy density: the energy density of DH4 is 2.0-4.0J/cm$^2$ and 2.3-4.5 J/cm$^2$ for DH5, DH5 Plus, DH5 Max while that of the primary predicate device is 1.8~5.1 J/cm$^2$ . The energy density of subject device is within the range of the minimum and maximum value of the primary predicate.
3. different pulse duration: the pulse duration of the device is 6.6-9.6ms, which is different from the primary predicate device, however it's within the range of the minimum and maximum value of both predicate devices, so this difference will not raise any safety or effectiveness issue.
Thus the subject device is determined to be substantially equivalent to the predicate devices.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

In order to verify and assure the performance, function and quality of the IPL Hair Removal Device, we have conducted the verification of output energy density, pulse duration time, valid times of flashes.

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
IEC 60601-1:2005/AMD1:2012/AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-11:2015/AMD1:2020 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 60601-2-83:2019 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
IEC 62471:2006 Photobiological safety of lamps and lamp systems

Clinical test is not applicable, thus, there's no clinical data for the device.
The subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.