April 10, 2023

Shenzhen Jizhimei 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: K230360
Trade/Device Name: IPL Cooling Hair Removal Device, Model(s): NBB01, NBB02
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: February 10, 2023
Received: February 10, 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 (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,

Colin K. Chen -S

for

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)*
K230360

Device Name
IPL Cooling Hair Removal Device
Model(s): NBB01, NBB02

Indications for Use *(Describe)*
The IPL Cooling Hair Removal 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.**

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

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

## I. Submitter

Shenzhen Jizhimei Technology Co., Ltd.
Building A203, Building A/B, Zone B, Gonghe Community, Shajing Street, Baoan District, Shenzhen, China
Post code: 518100
Tel.: +86 0755-86953535

Guo Miaosi
Legal representative
Tel: +86 15976876862
Email: 794796654@qq.com

## II. Device

**Name of Device:** IPL Cooling Hair Removal Device
**Model(s):** NBB01, NBB02
**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 Devices

### ➢ Primary Predicate Device

| Manufacturer | Primary Predicate Device | 510(k) Number | Approval Date |
|---|---|---|---|
| Shenzhen Qianyu Technology Co., Ltd. | Hand-held IPL device (JOVS Hair Removal Device) | K220645 | April 27, 2022 |

### ➢ Secondary Predicate Device

| Manufacturer | Predicate Device | 510(k) Number | Approval Date |
|---|---|---|---|
| Shenzhen Ulike Smart Electronics Co.,Ltd | IPL Hair Removal Device, Model(s): UI04A, UI04B, UI04C | K221002 | June 1, 2022 |

## IV. Device Description

IPL Cooling Hair Removal Device, is an over-the-counter, home-use device for unwanted hair reduction by using Intense Pulsed Light (IPL), and it has been designed two models with the same IPL technology for hair removal, which is model NBB01 and NBB02. The device works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain.

The device is only powered by the external power adapter and its IPL emission activation is by finger switch. The IPL Cooling Hair Removal Device has an irreplaceable light exit and it can cover an area of 3.6cm$^2$ that is suitable for multiple hair removal areas, such as face, lips, underarms, bikini lines, arms, legs, etc. 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 Cooling Hair Removal Device has 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.

## V. Indications for Use

The IPL Cooling Hair Removal 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 |
|---|---|---|---|
| IPL Cooling Hair Removal Device (Enclosure and light exit) | PC, ABS | 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 IPL Cooling Hair Removal Device (model: NBB01, NBB02) 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 subject device is safe and as effective as the predicate devices for its intended use. Therefore, the IPL Cooling Hair Removal Device may be found substantially equivalent to its predicate devices.

| Comparison Elements | Subject Device | Primary Predicate Device | Predicate Device | Remark |
|---|---|---|---|---|
| 510(k) Number | K230360 | K220645 | K221002 | / |
| Trade name | IPL Cooling Hair Removal Device | Hand-held IPL device (JOVS Hair Removal Device) | IPL Hair Removal Device, Model(s): UI04A, UI04B, UI04C | / |

| **Comparison Elements** | **Subject Device** | **Primary Predicate Device** | **Predicate Device** | **Remark** |
|---|---|---|---|---|
| Manufacturer | Shenzhen Jizhimei Technology Co., Ltd. | Shenzhen Qianyu Technology Co., Ltd. | Shenzhen Ulike Smart Electronics 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 IPL Cooling Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair. | Hand-held IPL device (JOVS Hair Removal Device) is an over-the-counter device intended for removal of unwanted body and/or facial 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 at 6, 9 and 12 months after the completion of a treatment regime. | Same |
| Prescription or OTC | OTC | OTC | OTC | Same |
| Applicable skin | Fitzpatrick skin types I-V | Unknown | Fitzpatrick skin types I-V | Same |
| Source energy | 100-240V, 50/60Hz | Unknown | 100-240V, 50/60Hz | Same |
| Power supply | Supplied by external adapter | Supplied by external adapter | Supplied by external adapter | Same |
| Dimension | NBB01: 47.6*54.3*240 mm NBB02-MAX: 235*76*43 mm | Unknown | 60.5(W)x38(H)x169.7(L) mm | Different **Note 1** |
| Sterilization | No | No | No | Same |
| Wavelength range | 550-1200mm | 590nm~1200nm | 550-1200mm | Same |
| Light source | Intense Pulsed Light | Intense Pulsed Light | Intense Pulsed Light | Same |
| Energy medium | Xenon Arc Flashlamp | Xenon lamp | Xenon Arc Flashlamp | Same |
| Energy density | 2~5./cm² (applicable for model NBB01) 2~4J/cm² (applicable for model NBB02) | 1.83~5.14J/cm² | 3.03-5.3J/cm² | Similar **Note 2** |

| **Comparison Elements** | **Subject Device** | **Primary Predicate Device** | **Predicate Device** | **Remark** |
|---|---|---|---|---|
| Output energy | Model NBB01:<br>8 ~ 17.05J<br>Model NBB02:<br>7.14 ~ 13.62J | 6.4~18 J | 10~17.5J | Similar<br>**Note 2** |
| Output intensity level | NBB01: 5 levels<br>NBB02: 6 levels | Unknown | 5 levels | Similar |
| Spot size | 3.6cm² (applicable for model NBB01 and NBB02) | 3.5cm² | 3.3cm² | Similar |
| Pulse duration | 6.4-7.2ms | 5.5~9.5 ms | 7-10ms | Similar<br>**Note 3** |
| Pulsing control | Finger switch | Finger switch | Finger switch | Same |
| Delivery device | Direct illumination to tissue | Direct illumination tissue | Direct illumination to tissue | Same |
| Software/ Firmware/ Microprocessor or Control? | Yes | Yes | Yes | Same |
| Biocompatibility | ISO10993-5<br>ISO10993-10 | Unknown | ISO10993-5<br>ISO10993-10 | Same |
| Electrical Safety | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>IEC 60601-2-83 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>IEC 60601-2-83 | IEC 60601-1-2<br>IEC 60601-1-11<br>ANSI AAMI ES60601-1<br>IEC 60601-2-57<br>IEC 60601-2-83 | Same |

Note 1:
Though the dimension is different from the predicate device, this difference is insignificant and do not raise any safety/effectiveness problems.

Note 2:
Though the energy density and the output energy of subject device is a little different from the primary predicate device, the energy density and the output energy of subject device is within the range of the minimum and maximum value of the primary predicate device, and the device complies with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Note 3:
Though the pulse duration of subject device is different from the primary predicate device, it's basically within the range of the primary predicate device, and the subject device complies with

IEC IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

## 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 Cooling 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 10993-10:2010 Biological Evaluation of Medical Devices –Part 10: Tests for Irritation and Skin Sensitization

**2) Electrical Safety and EMC**

Electrical safety and EMC testing was performed to, and passed, the following standards:

- ANSI AAMI ES60601-1 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.

## IX. Conclusions

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