August 12, 2022

Shenzhen Century Dongyuan Technology Co Ltd.
℅ You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.406, Building C, Run Science Park,
No.18 Shenzhou Road, Huangpu
Guangzhou, Guangdong 510663
China

Re: K221466
Trade/Device Name: IPL Hair Removal Device, model: AI01, AI06, AI08, AI16, AI17
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: May 19, 2022
Received: May 19, 2022

Dear You Yijie:

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
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)*

K221466

Device Name

IPL Hair Removal Device, model: AI01, AI06, AI08, AI16, AI17

Indications for Use *(Describe)*

The IPL Hair Removal Device (Model : AI01, AI06, AI08, AI16, AI17) is intended for the 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.**

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:

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*"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."*

# Section 5: 510(K) Summary

## 1. Submitter's Information

Establishment Registration Information:

| | |
|---|---|
| Name: | Shenzhen Century Dongyuan Technology Co Ltd. |
| Address: | Floor 2, Building B1, Gonghe Fourth Industrial Zone, Shajing Street, Bao'an District, Shenzhen City, Guangdong Province China |

Contact Person of applicant:

| | |
|---|---|
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Contact Person of the Submission:

| | |
|---|---|
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| FAX: | (+86)020-82245821 |
| Email: | jet.you@qimmiq-med.com |

**Date prepared: May 13, 2022**

## 2. Device Information

| | |
|---|---|
| Trade Name: | IPL Hair Removal Device, model: AI01, AI06, AI08, AI16, AI17 |
| Classification name: | Light Based Over-The-Counter Hair Removal |
| Common or Usual Name: | Powered Light Based Non-Laser Surgical Instrument With Thermal Effect |
| Review panel: | General & Plastic Surgery |
| Product code: | OHT |
| Regulation Class: | II |
| Regulation Number: | 878.4810 |

## 3. Predicate Device Information

| | |
|---|---|
| 510(k) submitter/holder: | Shenzhen Century Dongyuan Technology Co Ltd. |
| 510(K) Number: | K212897 |
| Trade Name: | IPL Hair Removal Device |
| Model: | AI01 |
| Classification name: | Powered Light Based Non-Laser Surgical Instrument With Thermal Effect |
| Review panel: | General & Plastic Surgery |
| Product code: | ONF |
| Regulation Class: | II |
| Regulation Number: | 878.4810 |

## 4. Device description

IPL Hair Removal Device, models: AI01, AI06, AI08, AI16, AI17 are hand-held over-the-counter devices for the permanent reduction of hair growth based on Intense Pulsed Light (IPL). The device is powered by an external power adapter and its IPL emission activation is by finger switch. The device contains a Xenon arc flashlamp, a skin sensor to detect appropriate skin contact, and a skin color detection system to detect the skin color. If the device is not properly applied to the treatment area (in full contact with the skin), the device cannot emit the treatment light pulses. The skin color detection system detects whether a skin tone is suitable for treatment. If the skin tone is not in the range suitable for treatment, the device is designed to not emit the treatment light pulses. The light pulses are selectively absorbed by the hair follicles, which results in the hair follicles being temporarily heated. This results in a reduction of hair growth from the treated hair follicles.

## 5. Indications for Use

The IPL Hair Removal Device (Model: AI01, AI06, AI08, AI16, AI17) is intended for the removal of unwanted body hair.

## 6. Summary of technological characteristics of device compared to the predicate devices (K212897)

| **SE Comparisons** | **Subject device (IPL Hair Removal Device, model: AI01, AI06, AI08, AI16, AI17)** | **Predicate device (IPL Hair Removal Device, model: AI01)** | **Discussion of difference** |
|---|---|---|---|
| 510K Number | / | K212897 | **/** |
| Classification | 21CFR 878.4810 | 21CFR 878.4810 | **Same** |
| Product Code | OHT | ONF | Technical Method equivalent, have same Classification regulation |

| | | | |
|---|---|---|---|
| FDA Class | II | II | **Same** |
| Model | AI01, AI06, AI08, AI16, AI17 | AI01 | **/** |
| Indications for Use | The IPL Hair Removal Device (Model: AI01, AI06, AI08, AI16, AI17) is intended for the removal of unwanted body hair. | The IPL Hair Removal Device (Model: AI01) is intended for the removal of unwanted body hair. | **Same** |
| Type of use | Over-The-Counter Use | Prescription Use | Different |
| Design | Hand-held | Hand-held | **Same** |
| Patient Population | Adult | Adult | **Same** |
| Technology | Intense Pulse Light (IPL) | Intense Pulse Light (IPL) | **Same** |
| Dimensions | 140*203*56 | 140*203*56 | **Same** |
| Power source | an external power supply | an external power supply | **Same** |
| Light source | Xenon Arc Flashlamp | Xenon Arc Flashlamp | **Same** |
| Wavelength | 510nm~1100nm | 510nm~1100nm | **Same** |
| Spot Size | 3.1 $cm^2$ | 3.1 $cm^2$ | **Same** |
| Max. Fluence ($J/cm^2$) | 3.8-5.2 J/cm² | 3.8-5.2 J/cm² | **Same** |
| Pulse duration | 3 milliseconds | 3 milliseconds | **Same** |
| Output energy | 12-16 J | 12-16 J | **Same** |
| Pulsing Control | Finger switch | Finger switch | **Same** |
| Skin contact sensor | Yes | Yes | **Same** |
| Skin Tone detection | Yes | No | Different |
| Software Control | Yes | Yes | **Same** |
| Electrical safety, EMC, Biological Evaluation | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>IEC 60601-2-57<br>IEC 62471<br>ISO 10993-5<br>ISO 10993-10 | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>IEC 60601-2-57<br>IEC 62471<br>ISO 10993-5<br>ISO 10993-10 | **Same** |

## 7. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The modifications to the device have been designed and assessed under design control processes compliant with FDA 21 CFR 820. A risk analysis was conducted to assess the impact of the changes on the subject device using internal design control procedures and a fault tree analysis described in the FDA-recognized version of ISO 14971.

These risks were mitigated using planned measures that included testing to recognized FDA consensus standards. Changes in software were verified and validated using the software development process.

Non-clinical testing listed in the table below was performed to demonstrate that the device can be used safely and effectively for the proposed indications for use.

| Standards | Standards Name | **Results** |
|---|---|---|
| ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 | Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance | Pass |
| IEC 60601-1-2: 2014 | Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests | Pass |
| IEC 60601-1-11: 2015 | Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests | Pass |
| ISO 60601-2-57: 2011 | Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use | Pass |
| IEC 62471: 2006 | Photobiological safety of lamps and lamp systems | Pass |
| ISO 10993-5:2009 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity | Pass |
| ISO 10993-10:2010 | Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization | Pass |
| IEC 62304:2006+A1:2015 | Medical device software - Software life cycle processes | Pass |

## 8. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

## 9. Conclusions

The subject device IPL Hair Removal Device models AI01, AI06, AI08, AI16, and AI17, in this 510(k) use the same IPL technology that is used in the predicate device K212897. Differences between the subject device models and predicate device do not raise new types of questions regarding safety and effectiveness, and performance testing demonstrates that the proposed device can be used safely and effectively for the proposed indications for use. The proposed IPL Hair Removal Device is considered to be substantially equivalent to the predicate K212897 device.