October 2, 2025

Shenzhen Enmind Technology Co., Ltd.
℅ Tangyao Dai
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: K251398
Trade/Device Name: IPL Hair Removal Device (IPL-001, IPL-002)
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: September 2, 2025
Received: September 2, 2025

Dear Tangyao Dai:

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.10.02 16:14:24 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K251398 |

Please provide the device trade name(s).

IPL Hair Removal Device (IPL-001, IPL-002)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

| 510(k) #: K251398 | 510(k) Summary | Prepared on: 2025-10-02 |
|---|---|---|

## Contact Details

21 CFR 807.92(a)(1)

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|---|---|
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## Device Name

21 CFR 807.92(a)(2)

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|---|---|
| Device Trade Name | IPL Hair Removal Device (IPL-001, IPL-002) |
| 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 |
|---|---|---|
| K230122 | Hair Removal Device, Model(s): UI04 SD, UI04 DG | OHT |
| K242710 | Hair Removal Device (R3C16-P, R3C16-W, R3C16-G, R3C16-P Pro, R3C16-W Pro, R3C16-G Pro, R3505-W, R3505-B, R3505-W Pro, R3505-B Pro) | OHT |
| K130315 | iPulse Hair Removal System | OHT |

## Device Description Summary

21 CFR 807.92(a)(4)

IPL Hair Removal Device is an over-the-counter, home-use and personal device for hair reduction by using 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.
IPL Hair Removal Device includes two models, IPL-001 and IPL-002. The two models adopt identical intended use, similar performance, operation and structure, with main differences in appearance, dimensions and weight, and light output parameters.
The device is only powered by the external power adapter. This device adopts light exit window (the IPL-002 adopts sapphire light exit window) that is suitable for multiple hair removal areas. The device is fitted with a skin sensor to detect appropriate skin contact, if the light exit 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 manual finger switch or auto light emission. Model IPL-002 has a cooling function that will be activated throughout the whole hair removal process to provide users with a more comfortable experience.

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

IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial 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 device have the same indications for use, both are used for unwanted hair removal.

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

The technical characteristic of IPL Hair Removal Device (IPL-001, IPL-002) are substantially equivalent to the predicate device and reference 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;

The difference between the subject device and the predicate devices mainly includes the following:
1. Wavelength range: The wavelength range of IPL-001 is 580-1200nm, and IPL-002 is 560-1200nm, which are not exactly the same as the predicate device, however, it's within the minimum range of the predicate device, so this difference will not raise any safety or effectiveness issue.
2. Energy density: The energy density of IPL-001 is 1.5-3.2J/$cm^2$ and IPL-002 is 2.7-5.5J/$cm^2$ which are different from that of the predicate device, however, they are within the range of the minimum and maximum value of the predicate and reference devices, so this difference will not raise any safety or effectiveness issue.
3. Pulse duration: The pulse duration of IPL-001 is 4.5ms-7ms, and IPL-002 is 11.5ms-15.5ms, which are different from that of the predicate device, however it's within the range of the minimum and maximum value of the predicate and reference 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 device and reference devices.

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

Non-clinical testing have been conducted to verify that the IPL Hair Removal Device meets all design specifications which supports the conclusion that it's substantially equivalent to the predicate device. The testing results demonstrate that the subject device complies with the following standards:
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 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
IEC 62471 Photobiological safety of lamps and lamp systems

The device software has been evaluated as per FDA guidance " Content of Premarket Submissions for Device Software Functions" .

Usability engineering study has been conducted and demonstrated conformance to FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff February 2016”.

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.

Clinical test is not applicable, thus, there's no clinical data for the device.

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