June 20, 2024

Ivylaser (Beijing) Technology Co., Ltd
℅ Owen He
Consultant
Microkn Medical Technology Service (Shanghai) Co.,Ltd.
Room 901, No. 889, Pinglu Road, Jing'an District
Shanghai,
China

Re: K240611
Trade/Device Name: IVYLASER Diode laser hair removal system (IVY-HR-Alloy)
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: GEX
Dated: May 13, 2024
Received: May 13, 2024

Dear Owen He:

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
Digitally signed by Tanisha L. Hithe -S
Date: 2024.06.20 14:44:11 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240611

Device Name

IVYLASER Diode laser hair removal system (IVY-HR-Alloy)

Indications for Use *(Describe)*

The Trio-Wavelength Handpiece combines 3 wavelengths (755+810+1064nm) into a single handpiece. It is intended for temporary hair reduction in Fast Hair Removal Mode(FHR).

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

Prepared on: 2024-06-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ivylaser (Beijing) Technology Co.,Ltd
Applicant Address	Room 411, Building 3, No. 2 Shengfang Road, Daxing District, Beijing Beijing Beijing China
Applicant Contact Telephone	010-62258470
Applicant Contact	Ms. Yuan Xiujuan
Applicant Contact Email	yuanxiujuan@oriental-laser.com
Correspondent Name	Microkn Medical Technology Service (Shanghai) Co., Ltd.
Correspondent Address	Room 901, No.889, Pinglu Road, Jing'an District, Shanghai Shanghai China
Correspondent Contact Telephone	+86 13524136210
Correspondent Contact	Mr. He Owen
Correspondent Contact Email	fda@microkn.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	IVYLASER Diode laser hair removal system (Model: IVY-HR-Alloy)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230580	Diode Laser System	GEX
K222064	The Alma Soprano Titanium	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The Trio-Wavelength Handpiece combines 3 wavelengths (755+810+1064 nm) into a single handpiece, which intended for temporary hair reduction in Fast Hair Removal Mode(FHR). It consists of a main unit, a foot switch and a handle-piece. The foot switch and the handle switch are activated to start emitting light pulses. The hand-piece has a cooled light outlet. The laser parameters and other system functions are controlled by a control panel on the main unit.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Trio-Wavelength Handpiece combines 3 wavelengths (755+810+1064nm) into a single handpiece.It is intended for temporary hair reduction in Fast Hair Removal Mode(FHR).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication for use is the same with predicate devices.They are intended for temporary hair reduction .

Technological Comparison

21 CFR 807.92(a)(6)

The pulse width, frequency and operation mode of proposed device is same as predicate device1 but similar to predicate device2. The wavelength is same as the both predicate devices .The spot size is similar to predicate device1 and different from predicate device2 .The maximum output energy counted by spot size is very close to predicate device1. All in all, the proposed device is considered would not raise any issues in safety and effectiveness and they can be considered substantially equivalent in safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical device Part1: 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 compatibility- Requirements and tests
- IEC/TR 60601-4-2:2016 Medical electrical equipment - Par4.2: Guidance and interpretation - electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-2-22:2007+A1:2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1:2014 Safety of laser products -Part 1: Equipment classification and requirements
- 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 delayed-type hypersensitivity

No clinical study is included in this submission.