April 24, 2025

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: K250206
Trade/Device Name: Diode laser system (Night Universe; Predator)
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: March 7, 2024
Received: January 24, 2025

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.

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: 2025.04.24 14:52:59 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*

K250206

Device Name

Diode laser system (Night Universe; Predator)

Indications for Use *(Describe)*

Diode laser system is used for hair removal, HR mode is for professional hair removal, and FHR is for rapid hair removal. The indications for use for the 810nm Diode Laser Module include: The HR mode and FHR mode are intended for hair removal and permanent hair reduction. Use on all skin types (Fitzpatrick I-VI) including tanned skin.
Permanent hair reduction is 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.

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510(k) #: K250206

510(k) Summary

Prepared on: 2025-01-24

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ivylaser (Beijing) Technology Co.,Ltd
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Correspondent Contact	Mr. Owen He
Correspondent Contact Email	fda@microkn.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Diode laser system (Night Universe; Predator)
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(s)	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222064	The Alma Soprano Titanium	GEX, ILY
K123483	Diode Laser	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The product is intended for the removal of unwanted body hair. It is suitable for all skin types, including tanned skin. The Diode laser system consists of the following main components.
1) The main unit, including the CPU main board, power supply module, control panel, service panel and cooling system.
2) Handlepiece, including the diode laser, TEC, handle switch, signal, cable and plug.
3) Foot switch.

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

Diode laser system is used for hair removal, HR mode is for professional hair removal, and FHR is for rapid hair removal. The indications for use for the 810nm Diode Laser Module include: The HR mode and FHR mode are intended for hair removal and permanent hair reduction. Use on all skin types (Fitzpatrick I-VI) including tanned skin.
Permanent hair reduction is 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 indication for use is the same with predicate devices. They are intended for the removal of unwanted body hair.

Technological Comparison 21 CFR 807.92(a)(6)

The device has the same technological characteristics as predicate devices in wavelength, energy density,operation model ,spot size,laser type, pulse width and frequency. And there is a little difference in cooling ways, weight and size, while it is considered would not raise any issues in safety and effectiveness and they can be considered substantially equivalent in safety and effectiveness.

We choose K222064 and Kl23483 as the equivalent products. The device has the same technological characteristics as predicate devices in wavelength: 810nm, energy density HR: 2J/cm - 60J/cm, FHR: 2J/cm-10J/cm, operation model: HR and FHR, spot size: 2 cm2, laser type: Diode Laser, pulse width: 5ms - 200 ms, and frequency HR: 1-3Hz, FHR: 5-10Hz. And there is a little difference in cooling ways (Water+air), weight: 60Kg; 33kg and size: Night Universe: 350mmX450mmX1000mm and Predator: 500mmX600mmX500mm.

However,such differences will not affect actual safety and effectiveness of this product, and we have also made a detailed analysis of this in the Substantial Equivalence Discussion in the document, Meanwhile, although there are slight differences in this product, However, all comply with the requirements of IEC 60601-1, IEC 60601-2-22, IEC 60601-1-2 and IEC/TR 60601 -4-2. The proposed device is as safe and effective as a legally marketed predicate devices, and does not raise new safety or effectiveness issues and the proposed device is substantially identical to the predicate devices.

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.

The subject device does not raise different types of safety or effectiveness questions. The conclusions drawn from these testing, and previously conducted testing of the predicate and legacy devices, demonstrate that the subject device is as safe, as effective, and performed as well as the predicates.
Thus, the subject device is substantially equivalent to its predicates.