April 15, 2026

Weifang Mingliang Electronics Co., Ltd.
Mingliang Li
General Manager
1-301, Bldg. 15, Phase 1, Yuandu Huizhi Industrial Complex
3999, Taixiang St.,Weifang Economic Development Zone
Shan Dong, 261000
China

Re: K260307
Trade/Device Name: Diode Laser Therapy Systems (V19)
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: December 11, 2025
Received: January 30, 2026

Dear Mingliang Li:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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: 2026.04.15 08:47:35 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260307

Device Name
Diode Laser Therapy Systems (V19)

Indications for Use *(Describe)*
Diode Laser Therapy Systems is intended to be used for hair removal of patients with hirsutism. It is indicated for use on all skin types (Fitzpatrick Skin Types 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) Summary - K260307

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Preparation: 11/12/2025

2. Sponsor Identification

Weifang Mingliang Electronics CO., LTD.
1-301, Building 15, Phase 1, Yuandu Huizhi Industrial Complex, No.3999, Taixiang Street,
Weifang Economic Development Zone, 261000, Shandong, P.R. China
Contact Person: xingzaisheng
Position: System Certification Specialist
Tel: +86-13406649353
Email: admin@mingliangkj.com

3. Identification of Proposed Device

Trade Name: Diode Laser Therapy Systems (V19)
Common Name: Powered Laser Surgical Instrument

Regulatory Information
Classification Name: Powered Laser Surgical Instrument
Classification: II
Product Code: GEX
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulation Medical Specialty: General & Plastic Surgery
Review Panel: General & Plastic Surgery

Indication For Use Statement:
Diode Laser Therapy Systems is intended to be used for hair removal of patients with hirsutism. It is indicated for use on all skin types (Fitzpatrick Skin Types 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.

4. Device Description

The Diode Laser Therapy Systems hair removal is based on the principle of selective photothermal dynamics, because the skin of human body is a relatively transparent structure. The laser can penetrate the skin very smoothly and reach the hair follicle, which is the position of hair growth. The melanin in the hair follicle absorbs a lot of laser energy and finally converts it into heat energy Make the temperature of hair follicle rise, so as to destroy the function of hair follicle, make hair lose the ability of regeneration, and then play the purpose of depilation.

Laser parameters and other system features are controlled from the control panel on the console, which provides an interface to the system's micro-controller through a LCD touch-screen.

In the handle of the machine, the light emitted by each discharge contains 808nm wavelengths.

5. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K212978
Product Name: Diode laser therapy system
Manufacturer: BEIJING UNT Technology Co., Ltd.

Reference Device 1
510(k) Number: K193426
Product Name: Elite iQ
Manufacturer: Cynosure, LLC

6. Non-Clinical Test Conclusion

Non-clinical testing was conducted to verify that the proposed device met design specifications. The test results demonstrated that the proposed device conforms to the following performance standards:

- EN ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-23:2021 Biological evaluation of medical devices- Part 10: Tests for skin sensitization
- EN ISO 10993-10:2023 Biological evaluation of medical devices- Part 10: Tests for irritation
- IEC 60601-1:2005 + A1:2012：Medical electrical equipment - Part 1: General requirements for basic safety and essential performance; Amendment 1
- IEC 60601-2-22:2019：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
- IEC 60601-1-2: 2014+A1：Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

7. Software Validation & Verification Testing

Software verification & validation testing were conducted and documentation was provided as recommended by FDA s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a a Basic Documentation level, since a failure or latent flaw in the software could directly result in erroneous diagnosis or a delay in delivery of appropriate medical care, which could result in minor injury.

8. Clinical Test Conclusion

No clinical study is included in this submission

9. Substantially Equivalent (SE) Comparison

Device Characteristic	Subject Device	Predicate Device (K212978)	Reference Device 1 (K193426)	Discussion
Trade name	Diode Laser Therapy Systems	Diode laser therapy system	Elite iQ	N/A
Product code	GEX	GEX	GEX	Same
Manufacturer	Weifang Mingliang Electronics CO., LTD.	BEIJING UNT Technology Co., Ltd.	Cynosure, LLC	N/A
Device Classification	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same
Intended Use	Diode Laser Therapy Systems is intended to be used for hair removal of patients with hirsutism. It is indicated for use on all skin types (Fitzpatrick Skin Types 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.	Diode Laser Therapy Systems is intended to be used for hair removal of patients with hirsutism. It is indicated for use on all skin types (Fitzpatrick Skin Types 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.	The Elite iQ Laser System is indicated for stable long-term or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 or 12 months after the completion of a treatment regime. It is used for skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Class	II	II	II	Same

Device Characteristic	Subject Device	Predicate Device (K212978)	Reference Device 1 (K193426)	Discussion
Configuration	Main Unit Handle Foot Control	Main Unit Handle Foot Control	Main Unit Handpiece Foot Control and Finger Control	Same
Laser type	Diode Laser	Diode Laser	Alexandrite	Same
Laser	Class IV	Class IV	Unknown	Same
Laser Wavelength	808nm	808nm	755nm	Same
Spot Size	12mm × 24mm=2.88cm²	1.2 cm×2.4 cm=2.88 cm²	2.5mm, 5mm, 7mm, 10mm, 12mm, 15mm, 18mm, 20mm, 22mm, & 24mm	Different 1
Fluence	100J/cm²	10-120 J/cm²	Up to 600J/ cm²	Different 2
Frequency	1-10 Hz	1-10 Hz	0.5-10 Hz	Same
Pulse Duration	1~200ms	10-300 ms	0.5-300ms	Different 3
Power Supply	110VAC (50/60Hz)	AC 100~230V/50/60Hz 2000VA	208V~240V/50~60Hz 5500VA	Different 4
Dimension	1260mm*560mm*700mm	430×500×1030mm	Unknown	Different 5
Weight	120kg	65kg	Unknown	Different 6
Patient Contacting Material	Aluminum alloy, Sapphire	Aluminum alloy, Sapphire	316 Stainless Steel	Same

Device Characteristic	Subject Device	Predicate Device (K212978)	Reference Device 1 (K193426)	Discussion
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Comply with ISO10993-1	Same
Sensitization	No evidence of Sensitization	No evidence of Sensitization		
Irritation	No evidence of Irritation	No evidence of Irritation		
Electrical Safety	Comply with IEC 60601-1 IEC 60601-2-22	Comply with IEC 60601-1 IEC 60601-2-22	Comply with IEC60601-1, IEC60601-1-22	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Laser safety	IEC 60825-1	IEC 60825-1	IEC 60825-1	Same

Comment

Different 1：The subject device's spot size of 12mm × 24mm yields an irradiation area of 2.88 cm^2, which is exactly equal to the area (2.88 cm^2) of the primary predicate device (K212978). The difference in unit representation (mm vs. cm) is non-substantive. The spot size array of the reference device further confirms that various spot dimensions are commercially available and cleared for the same intended use.

Different 2：The subject device utilizes a clinically equivalent single setting of 100 J/cm^2, which is solidly within the cleared range (10-120/125 J/cm^2) of all referenced predicates. This fixed parameter simplifies operation while ensuring energy delivery remains within the well-established and proven therapeutic window for safe and effective hair removal.

Different 3：The subject device operating range of 1-200 ms shares a substantial, clinically relevant overlap (10-200 ms) with the primary predicate device (K212978, 10-300 ms), ensuring equivalent laser-tissue interaction for hair removal. Furthermore, the lower end of our range is supported by the cleared parameters of the referenced device K193426, which has a validated range of 0.5-300 ms. This demonstrates that pulse durations at and below 10 ms are technically feasible and within the recognized safety profile of this device type.

Different 4：The differences in power supply specifications (e.g., 110VAC vs. 100-230VAC) reflect design adaptations for different regional electrical standards. These are external input specifications and do not affect the performance, calibration, or safety of the core therapeutic energy output system. The treatment delivery remains equivalent.

Different 5：The differences in physical dimensions are related to the device's industrial design, internal component layout, and cooling system architecture. These variations do not affect the device's intended use, its laser output parameters, treatment efficacy, or safety profile. The subject device remains a console-based system intended for use in a clinical setting, similar to the predicates.

Different 6：The increased weight correlates with the robust construction and use of materials that enhance device stability and longevity. This represents a performance improvement that does not adversely affect the devices deployment, operation, or safety profile. The core treatment mechanism remains unchanged

10. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K212978).