August 19, 2026

Hebei Zollvan Medical Technology Co., Ltd.
% Liya Meng
RA Manager
Tianjin Xinnuocheng Medical Technology Co., Ltd.
Rm. 1505, Wanhai Bldg., Dazhigu Sub-District
Hedong District
Tianjin, 300170
China

Re: K262070
Trade/Device Name: Diode Laser Therapy Systems (DL612A)
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: June 18, 2026
Received: June 22, 2026

Dear Liya Meng:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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: 2026.08.19 23:14:30 -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.

510(k) Number *(if known)*
K262070

Device Name
Diode Laser Therapy Systems (DL612A)

Indications for Use *(Describe)*
The Diode Laser Therapy Systems (DL612A) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

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: 2026/07/29

2. Sponsor Identification

Hebei Zollvan Medical Technology Co., Ltd
No.201,3rd Building, Zhidian Industrial Park, No.999 Fuxing East Road, Bailou Town, Lianchi District, Baoding, 071030 Hebei Province, China

Contact Person: Zhichao Ma
Position: R&D Manager
Tel: +86-18612170963
Email: 350987087@qq.com

3. Designated Submission Correspondent

Ms. Liya Meng

Tianjin Xinnuocheng Medical Technology Co., LTD.
Room 1505, Wanhai Building, Dazhigu Sub-district, Hedong District Tianjin, Hedong 300170 CHINA

Tel: +86-15620589932
Email: ra@tianjinxinnuochengyi.com.cn

4. Identification of Proposed Device

Trade Name: Diode Laser Therapy Systems (DL612A)
Common Name: Powered Laser Surgical Instrument

Regulatory Information
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification: II
Product Code: GEX
Regulation Number: 878.4810
Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

Predicate device:
510(k) Number: K211335
Product Name: Diode Laser Machine, Model Number: BM-100
Manufacturer: Zhengzhou Bestview St Co., Ltd.

6. Device Description

The proposed device incorporates a diode laser that emits invisible infrared laser radiation centered on a wavelength of 808 nm. It is mainly composed of main unit（include Power Supply Modules, System Controller, Cooling System and Display module ,Emergency stop switch and Foot switch） and handpiece.

The working principle of the system: The microprocessor controls the laser power supply to provide the laser module with an adjustable constant current. The high-power laser diode inside the laser module converts electrical energy into light energy, and outputs a continuous laser with a wavelength of 808nm.The laser beam passes through a light guide crystal When irradiated on the tissue to be depilated, it passes through the surface of the skin to reach the hair follicle. The light energy is absorbed and converted into heat energy that destroys the hair follicle tissue, so that the hair falls off and loses the ability to regenerate, achieving the purpose of hair removal.

7. Indication For Use Statement:

The Diode Laser Therapy Systems (DL612A) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type 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.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	**Proposed Device Diode Laser Therapy Systems**	**Predicate Device(K211335) Diode Laser Machine**	**Remark**
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	SAME
Classification	II	II	SAME
Product Code	GEX	GEX	SAME
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	SAME

Indications for use	The Diode Laser Therapy Systems (DL612A) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type 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 Diode Laser Machine (Model: BM-100) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type 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.	SAME
Prescription use or not	Prescription use	Prescription use	SAME

Table 2 Performance Comparison

Item	**Proposed Device Diode Laser Therapy Systems**	**Predicate Device(K211335) Diode Laser Machine**	**Remark**
Laser Type	Diode Laser	Diode Laser	SAME
Laser Classification	Class IV	Class IV	SAME
Laser wavelength	808 nm	808 nm	SAME
Spot Size	2.25 cm^2 (10mm x 22.5mm)	2.25 cm^2 (15mm x 15mm)	Analysis 1
Fluence (Energy Density)	FAST: 1-40J/cm^2 NORMAL：1-120J/cm^2	0-120 J/cm2	Analysis 2
Frequency	1-10 Hz	1-10 Hz	SAME
Pulse Duration	10-400 ms	10-400 ms	SAME
Power Supply	110~240VAC 50/60Hz	220/110 VAC/50Hz-60Hz	Analysis 3

Analysis:

Analysis 1-Spot Size

The areas of the spots are the same (both 2.25 cm^2).The difference in geometry would not impact the safety and effectiveness, because the final safety and effectiveness depends on the amount of energy output per unit area.

Analysis 2-Fluence (Energy Density)

The predicate device has a single fluence range of 0–120 J/cm², while the proposed device is split into FAST(1–40 J/cm²) and NORMAL(1–120 J/cm²). The fluence of the proposed device is fully covered within the predicate's fluence range.

Analysis 3-Power Supply

The Power Supply of proposed device is different with the predicate device, but the proposed device has been conducted as IEC 60601-1 and IEC 60601-1-2, the results shown that, there is no effect the effectiveness and safety.

9. Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications and to support the Substantial Equivalence determination.

Biocompatibility testing

Testing was conducted to demonstrate that the proposed device complies with the following standards:

- ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

Electrical safety and electromagnetic compatibility (EMC)

Testing was conducted to demonstrate that the proposed device complies with the following standards:

- AAMI/ANSI ES60601-1:2005(R) 2012 and A1:2012, Medical electrical equipment - Part 1: 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 disturbances - Requirements and tests
- IEC TS 60601-4-2 Edition 1.0 2024-03 Medical electrical equipment - Part 4-2: Guidance and interpretation- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Laser Safety

Testing was conducted to demonstrate that the proposed device complies with the following standards:

- IEC 60601-2-22 Edition 4.0 2019-11, 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

Software Verification and Validation Testing

Software verification and 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 documentation level for this device was determined to be "basic."

Specification Testing

Testing was conducted to validate that the proposed device meets technical specifications for wavelength, fluence, pulse duration, spot size, and frequency.

10. Clinical Testing

No clinical study is included in this submission.

11. Conclusion

The data obtained from the nonclinical tests support that the device is as safe, as effective, and performs as well as the legally marketed predicate device.