August 8, 2025

Hebei Newangie Technology Co., Ltd
% Wang Ray
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, 102401
China

Re: K251801
Trade/Device Name: Diode laser device (BM091)
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 12, 2025
Received: June 12, 2025

Dear Wang Ray:

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: 2025.08.08 11:21:00 -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

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.	K251801

Please provide the device trade name(s).

Diode laser device (BM091)

Please provide your Indications for Use below.

The Diode laser device 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.

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)

The assigned 510(k) Number: K251801

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 2025.06.11
2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Diode laser deviece

Model: BM091

Common Name: Powered Laser Surgical Instrument

Regulatory Information
Classification Name: Powered Laser Surgical
Instrument Classification: II
Product Code: GEX
Regulation Number: 878.4810
Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

510(k) Number: K232709
Product Name: Diode laser therapy device
Manufacturer: Hebei Zhemai Technology Co., Ltd

Reference Device:
510(k) Number: K241642
Product Name: Diode Laser Hair Removal System (MBT-Diode Laser)
Manufacturer: Beijing Mega Beauty Technology Co.,Ltd.

6. Device Description

Diode laser device consists of a main unit, a handheld, a foot switch and a power cord.
Device composition and handle characteristics: The device includes a handle with a single-band 808nm semiconductor laser, and the semiconductor lasers of the handle are powered by the laser power supply in the host to emit the laser of the corresponding wavelength.
Working principle of semiconductor laser: Semiconductor laser uses semiconductor materials of different doping types as laser working substance, uses natural cleavage surface to form resonant cavity for laser oscillation and amplification, and adds forward voltage to PN junction area of semiconductor laser to form particle number inversion of non-equilibrium carrier between conduction band and valence band of semiconductor substance. When a large number of electrons and holes in particle number inversion state are recombined, excess energy will be released, and these energies will be expressed in the form of photons, that is, laser is formed. Due to resonance amplification of cleavage surface resonant cavity, stimulated feedback is realized, so that laser can be directionally emitted and output from semiconductor laser.

7. Indication For Use Statement:

Diode laser device 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

Tab 1 General Comparison

Item	**Proposed Device**	**Predicate Device K232709**	**Reference Device K241642**	**Remark**
Device Name	Diode laser device	Diode laser therapy device	Diode Laser Hair Removal System	
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	II	II	II	SAME
Product Code	GEX	GEX	GEX	SAME
Indication for use	The Diode laser device 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 therapy device 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 Hair Removal System (Model: MBT-Diode Laser) 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

Tab 2 Performance Comparison

Item	**Proposed Device**	**Predicate Device K232709**	**Reference Device K241642**	**Remark**
Laser Type	Diode Laser	Diode Laser	Diode Laser	SAME
Laser Classification	Class IV	Class IV	Class IV	SAME
Laser wavelength	808 nm	808 nm	808 nm	SAME

Spot Size	12mm x 20mm	12mm × 35mm	15mm × 15mm	Different1
Fluence	2-60j/cm2	5-100 J/cm2	1-55.96j/cm2	Different2
Frequency	1-10HZ	1-10HZ	1-10HZ	SAME
Pulse Duration	5-200ms	5-200ms	2-240ms	SAME
Power Supply	AC100-240V/50-60Hz	AC110-240V/60Hz	AC110-240V/50-60Hz	SAME
Dimension	375mm*440mm*1170mm	55cm*55cm*123cm	650mm*580mm*1210mm	Different3
Weight	63kg	62kg	68kg	Different4

Analysis

Different1-Spot Size

The proposed device is different in Spot Size from the predicate, Spot size only affects the area of treatment, not affect the therapeutic effect. Therefore, this difference will not affect the safety and effectiveness.

Different2-Fluence

The proposed device has different Fluence from the predicate device.

For the difference on fluence between the predicate and proposed device, The Fluence of Predicate Device K232709 is 5-100J/cm2, while the propose device is 2-60 J/cm2.It is lower than 100 J/cm2, the safety of the product is no problem. However, the effectiveness cannot be determined, so we selected Reference Device K241642 with the same intended use for Fluence comparison,The Fluence of the Reference Device is 1-55.96J/cm2, which is similar to the Fluence of the proposed device, so the effectiveness of the product is not affected. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

Different3/4- Dimension/ Weight

The proposed device is different in dimension and weight from the predicate device. However, the dimension and weight difference are just in physical specification and this difference will not raise any issues in safety and effectiveness. By complying with AAMI/ANSI/ES 60601-1, the mechanical performance of the proposed device is determined to be accepted. Therefore, this difference will not affect safety and effectiveness of the proposed device.

9. Non-Clinical Test Conclusion

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 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements
- IEC 60601-2-22: 2012 Medical electrical equipment - Part 2-22: Particular requirements for

basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

- ISO 10993-10 Fourth edition 2021, 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
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- IEC 60601-1-2 Edition 4.1 2020-09, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Test

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

Based on the non-clinical tests performed, the subject device is as safe, as effective, and performance as well as the legally marketed predicate device, Diode laser therapy device leared under K232709.