



November 30, 2023

Hebei Zhemai Technology Co., Ltd
Ray Wang
Official Correspondent
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China

Re: K232709

Trade/Device Name: Diode laser therapy device
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: September 4, 2023
Received: September 5, 2023

Dear Ray Wang:

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. Tanisha L. Hithe -S
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16:26:37 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name

Diode laser therapy device

Indications for Use (Describe)

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.

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

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

The assigned 510(k) Number: K232709

1. Date of Preparation: 10/31/2023

2. Sponsor

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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: Diode laser therapy device

Common Name: Powered Laser Surgical Instrument

Model(s): FD-L01

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

Review Panel: General & Plastic Surgery

Indication For Use Statement:

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.

5. Device Description

Diode Laser Hair Removal adopts Gold standard 808nm semi-conductor laser, based on selective photothermolysis principle, through specific wavelength, penetrate epidermis into dermis, optical energy was absorbed and translated into heat energy with restraining hair follicle tissues, and produce photothermal effect. It takes laser energy in hair follicle with rich in melanin, surrounding tissues absorb less even no energy, reach to restrained melanin of hair follicles and remove hair. Meanwhile, don't hurt around tissues and virtually pain-free remove surplus hair; eventually, reach to permanent Hair Removal.

The Diode laser therapy device utilize a semiconductor diode with invisible infrared radiation as a laser source to emit 808nm wavelength laser which is absorbed by melanin. The laser power is delivered to the treatment area via laser handpiece. The emission laser is activated by a foot-switch.

6. Predicate Device Identification**Predicate Device:**

510(k) Number: K210663

Product Name: Dermatological Diode Laser Systems

Model: CM01D

Manufacturer: Beijing HuaCheng Taike Technology Co., Ltd.

7. 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 60601-1-2: 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- AAMI/ANSI ES 60601-1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- 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
- ISO 10993-5: 2009 Biological evaluation of medical device - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 14971: 2019 Medical devices - Application of risk management to medical devices

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 6-1 General Comparison

ITEM	Proposed Device	Predicate Device (K210663) Model: CM01D	Remark
Product Code	GEX	GEX	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	2	2	SAME
Indication for Use	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 Dermatological Diode Laser Systems (Model: CMO2D) 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
Configuration	Main Unit	Main Unit	SAME
	Handpiece	Handpiece	SAME
	Foot Control	Foot Control	SAME
Principle of Operation	Diode Laser	Diode Laser	SAME

Table 6-2 Performance Comparison

ITEM	Proposed Device	Predicate Device (K210663) Model: CM01D	Remark
Laser Type	Diode Laser	Diode Laser	SAME

Laser Classification	Class IV	Class IV	SAME
Laser wavelength	808 nm	808 nm	SAME
Spot Size	12mm × 35mm	10 × 30 mm	Analysis 1
Fluence	5-100 J/cm ²	5-100J/cm ²	SAME
Frequency	1-10 Hz	1-10Hz	SAME
Pulse Duration	5-200ms	15-400ms	Analysis 2
Power Supply	AC 110V/60Hz	AC 110V/60Hz	SAME
Dimension	55cm × 55 cm × 123cm	65cm × 65cm × 123cm	Analysis 3
Weight	62kg	75kg	Analysis 4

Analysis 1:

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.

Analysis 2:

The proposed device is difference in Pulse Duration with the predicate device. The frequency of the proposed device is within the range of that of the predicate device, which can justify that the difference in the parameter of Pulse duration will not raise new safety issues of the proposed device. In addition, we also found a reference device (K181019), which has the same intended use as the reference device. The Pulse Duration of the reference device is 30-200 ms, which is similar to the proposed device's pulse duration, so this difference will not affect the effectiveness of the device.

In summary, this difference will not affect safety and effectiveness of the proposed device.

Analysis 3/4:

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.

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 (K210663).