November 18, 2024

Hebei Keylaser Sci-Tech Co., Ltd.
% Ray Wang
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: K241498
Trade/Device Name: Diode laser Treatment System (K18)
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: October 18, 2024
Received: October 18, 2024

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.

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: 2024.11.18 14:24:52 -05'00'

Tanisha Hithe
Assistant Director
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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)*

K241498

Device Name

Diode laser Treatment System (K18)

Indications for Use *(Describe)*

The Diode laser Treatment System (Model: K18) 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 21 CFR 807.92.

The assigned 510(k) Number: K241498

1. Date of Preparation: 11/15/2024

2. Sponsor

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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: Diode laser Treatment System
Common Name: Powered Laser Surgical Instrument
Model(s): K18

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 Treatment System (Model: K18) 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 Treatment System 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.

The Diode laser Treatment System 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: K221312
Product Name: Diode Laser Hair Removal Device
Model: M-I-X MEDICAL
Manufacturer: Guangzhou CHUANG ZAO MEI 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: 2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- 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
- 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
- IEC 60825-1: 2007 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: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- IEC TR 60601-4-2: 2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	**Proposed Device**	**Predicate Device (K221312)** Model: M-I-X MEDICAL	Remark
Product Code	GEX	GEX	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	2	2	SAME
Indications for use	The Diode laser Treatment System (Model: K18) 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 Device (Model: EVOLUTION MEDICAL, M-I-X MEDICAL) 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
Laser Type	Diode Laser	Diode Laser	SAME
Laser Classification	Class IV	Class IV	SAME
Laser wavelength	808 nm	808 nm	SAME
Spot Size	12mm × 24mm	12.6mm × 20.6mm	Analysis 1
Fluence	1-70J/cm^2	1-70J/cm^2	SAME
Frequency	1-10 Hz	1-10Hz	SAME
Pulse Duration	3-320ms	3-320ms	SAME
Power Supply	AC 110V, 50Hz/60Hz	AC 120V/60Hz	Analysis 2
Dimension	460×370×1150mm	393mm×430mm×1130mm	Analysis 2
Weight	52kg	48kg	Analysis 2

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 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 IEC 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.

Table 2 Test Comparison

ITEM	**Proposed Device**	**Predicate Device (K221312)** Model: M-I-X MEDICAL	**Remark**
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with ANSI/AAMI ES60601-1, IEC 60601-2-22	Analysis 3
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SAME
Patient Direct/Indirect Contact Materials and Biocompatibility			
Patient Direct/Indirect Contact Materials	Gemstone	Tip of Handle (6063 Aluminum & S1 Quartz)	Analysis 4
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SAME
Sensitization	No evidence of sensitization	No evidence of sensitization	SAME
Irritation	No evidence of irritation	No evidence of irritation	SAME

Biocompatibility testing standards	Comply with ISO 10993-5, ISO 10993-10, ISO 10993-23	Comply with ISO 10993-5, ISO 10993-10	Analysis 3

Analysis 3:

The proposed device is different in Electrical Safety Testing Standard and Biocompatibility Testing Standard from the predicate device. The proposed device was tested according to IEC 60601-1:2020, ISO 10993-5:2009, ISO 10993-10:2021 and ISO 10993-23:2021, which are FDA recognized standard. Therefore, this different will not affect safety and effectiveness of the proposed device.

Analysis 4

The subject and predicate device have different Patient Direct/Indirect Contact Materials, the contact material of the subject device is gemstone. By complying with ISO 10993-5, ISO 10993-10, ISO 10993-23, the material of proposed device is determined to be accepted. Therefore, this different 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 the legally marketed device (K221312).