April 23, 2021

Zhuolu Jontelaser Manufacturing Technology Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
Rm. 912, Building #15, XiYueHui, No.5, YiHue North Rd.,
FangShan District
BeiJing, BeiJing 102401
China

Re: K202257
Trade/Device Name: Dermatological Diode Laser Systems
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: March 23, 2021
Received: March 26, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Purva Pandya
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)*
K202257

Device Name
Dermatological Diode Laser Systems

Indications for Use *(Describe)*
The Dermatological Diode Laser Systems 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.

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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 Title 21, CFR Section 807.92.

1. Date of Preparation

   08/06/2020

2. Applicant Name and Address

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4. Submission Correspondent

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5. Identification of Proposed Device

Trade Name: Dermatological Diode Laser Systems
Common Name: Powered Laser Surgical Instrument
Model(s): T5 Pro/T8 Pro

Classification Name: Powered Laser Surgical Instrument
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810;
Review Panel: General& Plastic Surgery;

6. Identification of Primary Predicate
510(k) Number: K192569
Product Name: Diode Laser Therapy System
Manufacturer: San He Lefis Electronics Co., Ltd.

7. Device Description

The proposed device, Diode Laser Therapy System, is a surgical device, which is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI);

There are 2 models included, T5 Pro and T8 Pro, the two models have same intended use, mechanism of action, principle and specification, only difference is the configuration. The detailed difference shown as following:

Table 1 The Difference of Models

Model	T5 Pro	T8 Pro
Size	63*52*46cm	49*44*139cm
Weight	48Kg	57Kg

The main components of proposed device shown as following:

Table 2 Main Components of Proposed Device

Components	Function Description	Applied Model(s)
Handpiece	Deliver the laser to area to be treated	T5 Pro/T8 Pro
Touchscreen	The user interface and for controlling of the system	T5 Pro/T8 Pro
Emergency Switch	Stop the system in case of emergency situation	T5 Pro/T8 Pro
Key Switch	Start the system	T5 Pro/T8 Pro
Connector	Connection of the device with the handpiece	T5 Pro/T8 Pro
Indicator Lamp	Indicate current working state of the appliance	T5 Pro/T8 Pro
Foot Switch	Activate the laser emission	T5 Pro/T8 Pro

8. Indication For Use

The Dermatological Diode Laser Systems 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.

9. Substantially Equivalent (SE) Comparison

Table 3 General Comparison

ITEM	Proposed Device	Predicate Device	Remark
Product Code	GEX	GEX	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	2	2	SAME
Where used	Hospital	Hospital	SAME
Intended Use	The Dermatological Diode Laser Systems 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 System 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 4 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark
Laser Type	Diode Laser	Diode Laser	SAME
Laser Classification	Class IV	Class IV	SAME
Laser wavelength	808 nm	808 nm	SAME
Spot Size	2.4 cm2	2.8 cm2	Analysis 1
Fluence	2-40 J/cm2	2-40 J/cm2	SAME
Frequency	1-10 Hz	1-10 Hz	SAME
Pulse Duration	10-400 ms	3-400 ms	Similar
Power Supply	AC 100-240V/50Hz-60Hz	AC 110V/50Hz-60Hz	SAME

Dimension	49*44*139cm	51*60*100cm	Analysis 2
	63*52*46cm		
Weight	57KG	45kg	Analysis 3
	48KG		

Table 5 Safety Comparison

Item	Proposed Device	Predicate Device	Remark
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SAME
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 Contact Materials and Biocompatibility			
Patient Contact Materials	Quartz in handpiece and handpiece tip (aluminum and SiO2)	Stainless steel and Sapphire in handpiece	Analysis 4
Cytotoxicity	No Cytotoxicity	Comply with ISO 10993-1	SAME
Sensitization	No evidence of sensitization		
Irritation	No evidence of irritation		

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 substantially equivalency.

Analysis 2/3

The proposed device is different in dimension and weight from the predicate device, because the proposed device is a trolley type, while the predicate device is a desktop type. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted, therefore, this difference will not affect the substantially equivalency.

Analysis 4

The proposed device is different in patient-contacting materials. But all patient-contacting materials used in proposed device has been evaluated as ISO 10993-1, as the results of evaluation, there is no biocompatibility concerns raised from the patient-contacting materials used in proposed device, so this different will not affect the substantially equivalency.

10. 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 60601-1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-22:2007, 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, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility-Requirements and tests.
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity
- Software Validation & Verification Test

11. Clinical Testing

No clinical study is included in this submission.

12. Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.