January 14, 2022

Beijing Stelle Laser Technology 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, Beijing 102401
China

Re: K212478
Trade/Device Name: Dermatological diode laser system
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: December 1, 2021
Received: December 9, 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)*
K212478

Device Name
Dermatological diode laser system

Indications for Use *(Describe)*
The Dermatological diode laser 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.

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.

The assigned 510(k) Number: K212478

1. Date of Preparation

   01/13/2022

2. Sponsor

Beijing Stelle Laser Technology Co., Ltd.
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3. Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Dermatological diode laser system
Common Name: Powered Laser Surgical Instrument
Model(s): ADPL2/ALD1/DPL4/LD1

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

Indication for Use:

The Dermatological diode laser 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.

5. Device Description

The Dermatological Diode Laser Systems 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 s laser handpiece. The emission laser is activated by a foot-switch.
The laser light targets on melanin and treat selectively in a precise way. Melanin could absorb the energy from the laser, which would result in temperature rapid increase, to destroy germinal cell and does not damage epidermis and the surrounding normal tissue. After laser exposure, the debris of these cells is removed from the body by phagocytic cells.

The four models of different products produced by our company are consistent in Wavelength ， Energy Fluence， Pulse Duration， Energy deviation， Spot Size， Frequency and so on. It's just that the shell is slightly different.

	ADPL2	ALD1	DPL4	LD1
Wavelength	808nm±10nm	808nm±10nm	808nm±10nm	808nm±10nm
Energy Fluence	1-120J/cm^2 (Adjustable)	1-120J/cm^2 (Adjustable)	1-120J/cm^2 (Adjustable)	1-120J/cm^2 (Adjustable)
Pulse Duration	10-400 ms	10-400 ms	10-400 ms	10-400 ms
Energy deviation	±20%	±20%	±20%	±20%
Spot Size	12*12mm	12*12mm	12*12mm	12*12mm
Frequency	1-10Hz	1-10Hz	1-10Hz	1-10Hz

Pictures of four models of shell:

ADPL2

ALD1

DPL4

LD1

6. Identification of Predicate Device

Predicate Device
510(k) Number: K162659
Product Name: Diode Laser Hair Removal System
Manufacturer: Shandong Huamei 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:

- AAMI ES60601-1:2005+A1:2012 Medical Electrical Equipment - Part 1: General Requirements for 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: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2007, 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 10993-10:2002/Amd. 1: 2006, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1
- Performance Testing for Spot Size Accuracy and Energy Output Accuracy.
- Software Validation & Verification Test

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device(K212478)	Predicate Device（K162659）	Remark
Product Code	GEX	GEX	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	Same

Class	2	2	Same
Intended Use	The Dermatological diode laser 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.	The Diode Laser 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 2 Performance Comparison

ITEM	Proposed Device(K212478)	Predicate Device（K162659）	Remark
Laser Type	Diode Laser	Diode Laser	Same
Laser Classification	Class IV	Class IV	Same
Laser wavelength	808 nm	808 nm	Same
Spot Size	12×12mm	14×14mm	Analysis 1
Fluence	120J/cm²	1-120J/ cm2	Same
Pulse Duration	10-400ms	5-400ms	Similar
Power Supply	100/110V,50/60Hz or 230-260V,50/60Hz	AC 110V/60Hz	Analysis 2
Dimension	519mm×923mm×474mm	450mm× 550mm×380mm	Analysis 3
Weight	42Kg	52Kg	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 substantially equivalency.

Analysis 2

The proposed device is different in fluence from the predicate device, the difference is very slight. Frequency of proposed device is within the predicate device. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test (Energy density and Spot Size), the safety and performance of the product can be ensured. So the proposed device is determined to be substantially equivalency with predicate device.

Analysis 3/ 4

The proposed device is different in dimension and weight from the predicate device. 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 substantial equivalency.

Table 3 Safety Comparison

Item	Proposed Device(K212478)	Predicate Device（K162659）	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 Indirect Contact Materials	ABS plastic. Metal aluminum. Window Quartz	Sapphire in handpiece	Similar
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

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device. Any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness.