March 31, 2023

Shanghai Omni Laser Skinology Co., Ltd.
% Helen Nan
General Manager
New Risen Enterprise Management Consulting Co., Ltd.
Room 302, Building 3, Hangqian Mansion, Hangqian Street,
Lucheng District
Wenzhou, Zhejiang 325000
China

Re: K223778
Trade/Device Name: Diode Laser Hair Removal System (RD-SLD600)
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 6, 2023
Received: March 6, 2023

Dear Helen Nan:

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,

Jianting Wang -S

Jianting Wang
Acting 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.

Submission Number *(if known)*

K223778

Device Name

Diode Laser Hair Removal System (RD-SLD600)

Indications for Use *(Describe)*

Diode Laser Hair Removal System (RD-SLD600) 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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K223778 510(k) Summary
(As required by 21 CFR 807.92)

1.0 Submitter Information

Company:	Shanghai Omni Laser Skinology Co., Ltd.
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Phone:	+86-021-54847192
E-mail:	avril@omni-laser.com
Contact	Avril Ouyang
Title:	General Manager

2.0 Device Information

Trade/Device Name:	Diode Laser Hair Removal System
Model:	RD-SLD600
Device:	Powered Laser Surgical Instrument
Review Panel:	General & Plastic Surgery
Product Code:	GEX
Submission Type:	Traditional 510(k)
Regulation Number:	CFR 878.4810
Device Class:	Class II

3.0 Predicate Device Information

Predicate Device #1:

Trade/Device Name:	Diode Laser Hair Removal System
510k Number:	K162659
Submitter:	Shandong Huamei Technology Co.,ltd.

Predicate Device #2:

Trade/Device Name:	The Diode Laser Machine
510k Number:	K211335
Submitter:	Zhengzhou Bestview St Co., Ltd

4.0 Indications for Use

Diode Laser Hair Removal System (RD-SLD600) 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.

5.0 Device Description

The proposed device, Diode Laser Hair Removal System (RD-SLD600) is a professional platform, it is intended for the removal of unwanted hair and to effect stable, long-term hair reduction on all skin types (Fitzpatrick skin type I-VI).

The complete system consists of its console, module and a footswitch. The module is

pressed against the patient’s skin and a light pulse is delivered when the emitted button or the footswitch are activated. The crystal contact surface is cooled by the RD-SLD600’s cooling system.

Output parameters and other system features are controlled from the touch-screen control panel on the console, which provides an interface to the system's microcontroller through and LCD touch-screen.

6.0 Comparison of Technological Characteristics with the Predicate Device

Table 1 - General Comparison

Device Feature	Subject Device	Predicate Device #1	Predicate Device #2	Comparison
Name	Diode Laser Hair Removal System RD-SLD600	Diode Laser Hair Removal System HM-DL100	The Diode Laser Machine BM-100	-
Product Code	GEX	GEX	GEX	SE
Indications for use	Diode Laser Hair Removal System (RD-SLD600) 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.	The Diode Laser Machine (Model: BM-100) 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.	SE
Configuration	Main Unit	Main Unit	Main Unit	SE
	Handpiece	Handpiece	Handpiece	
	Foot Control	Foot Control		
Principle of Operation	Diode Laser	Diode Laser	Diode Laser	SE

Table 2 - Performance Comparison

Device Feature	Subject Device	Predicate Device #1	Predicate Device #2	Comparison
Laser Type	Diode Laser	Diode Laser	Diode Laser	SE
Laser Classification	Class IV	Class IV	Class IV	SE
Wavelength	808 nm	808 nm	808 nm	SE
Spot Size	2.0 cm^2 (10*20mm)	1.44 cm^2	2.25 cm^2 (15*15mm)	Discussion
Fluence	40-120 J/ cm^2	1-120 J/ cm^2	0-120 J/cm^2	SE
Irradiance	1-300 W/cm^2	0.7-347.8 W/cm^2	Not publicly available	SE
Frequency	1-10 Hz	0.5-15 Hz	1-10 Hz	Discussion
Pulse Duration	1-100 ms	5-400 ms	10-400 ms	Discussion
Power Supply	AC 100-240V, 50-60 Hz	AC 110V/60Hz	220/110 VAC/50Hz-60Hz	SE
Dimension	45.7cm * 38.5cm *104cm	45cm * 55cm * 38cm	112 cm * 42 cm * 60cm	Discussion
Weight	50 KG	52 KG	63 KG	Discussion

Table 3 Safety Comparison

Item	Subject Device	Predicate Device #1	Predicate Device #2	Comparison
Patient Contact Materials	K9 Crystal in handpiece	Sapphire in handpiece	handpiece	Discussion
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SE
Sensitization	No evidence of sensitization	No evidence of sensitization	No evidence of sensitization	SE
Irritation	No evidence of irritation	No evidence of irritation	No evidence of irritation	SE
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SE

EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SE

7.0 Discussion of Tests Performed

7.1 Clinical Tests

Clinical testing was not performed for the subject device as part of the submission.

7.2 Non-Clinical Tests

The following performance data are provided in support of the substantial equivalence determination:

- Electrical Safety and Electromagnetic Compatibility (EMC)

  ES60601-1:Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance;

  IEC 60601-1-2: Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility

  IEC 60601-2-2, 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, Safety of laser products - Part 1: Equipment classification and requirements

- Biocompatibility

  ISO 10993-5: Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.

  ISO 10993-10: Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

The conclusion from the testing is the device is safe and effective for its intended use, and performs as well or better than the predicate devices.

8.0 Software

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

9.0 Conclusion

The Diode Laser Hair Removal System (RD-SLD600) is as safe and effective as its predicate devices. The Diode Laser Hair Removal System (RD-SLD600) has the same intended use and same technological characteristics and specifications as its predicate devices. Thus, the Diode Laser Hair Removal System (RD-SLD600) is substantially equivalent to its predicate devices.