August 16, 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: K230342
Trade/Device Name: Phototherapy System (OL-PDT950)
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: July 17, 2023
Received: July 17, 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

For Tanisha L. Hithe, MS, MHS
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.

510(k) Number *(if known)*
K230342

Device Name
Phototherapy System (OL-PDT950)

Indications for Use *(Describe)*
he Phototherapy System use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.
The blue light (469nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
The red light (633nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions.
The infrared light (835nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

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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K230342_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

Prepared date: 07/17/2023

2.0 Device Information

Trade/Device Name:	Phototherapy System
Model:	OL-PDT950
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:

K Number：	K200751
Trade/Device Name:	Photodynamic Therapy System
Submitter:	Shangdong Huamei Technology Co., Ltd.

Predicate Device 2

K Number：	K222751
Trade/Device Name:	LED Light Therapy Device
Submitter:	Xuzhou Kernel Medical Equipment Co., Ltd.

Predicate Device 3

K Number：	K200104
Trade/Device Name:	Oxylight
Submitter:	RAJA Trading Company, Inc.

4.0 Indications for Use

The Phototherapy System use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.

The blue light (469nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

The red light (633nm wavelength) is generally indicated to treatment of superficial,

benign vascular, and pigmented lesions.

The infrared light (835nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

5.0 Device Description

The Phototherapy System OL-PDT950 is a vertical device which uses specific wavelengths of light, produced by LEDs (Light emitting diodes), to manage aesthetic conditions.

The device produces light in the red light region of the spectrum (633±15nm), in the blue light regions of the light spectrum (469±15nm) and infrared light region of light spectrum (835±15nm).

Five sets of LEDs panels are available for the device.

6.0 Discussion of Tests Performed

6.1 Clinical Tests

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

6.2 Non-Clinical Tests

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

IEC 60601-1: 2005 + CORR.1:2006 + CORR.2:2007 + A1:2012: Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance;

IEC 60601-1-2: 2014: Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility

IEC60601-2-57:2021: Medical electrical equipment -- Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use;

IEC 62471: 2006: Photobiological safety of lamps and lamp systems.

7.0 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".

8.0 Comparison of Technological Characteristics with the Predicate Device

Table 1 - General Comparison

Device Feature	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3
K Number	K230342	K200751	K222751	K200104
Name	Phototherapy System	Photodynamic Therapy System	LED Light Therapy Device	OxyLight
Product Code	GEX	GEX	GEX	GEX
Indications for use	The Phototherapy System use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The blue light (469nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The red light (633nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The infrared light (835nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of	The Photodynamic Therapy (PDT) Equipment use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The blue light (415nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The red light (630nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The infrared light (835nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness;	LED Light Therapy Device use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The red light (633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The blue light (417±10 nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The Yellow light (599±10nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides.	The Oxylight is intended for dermatological use by physicians and healthcare professionals for the following: LED Technology is intended for: Blue LED – 465nm – to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. Red LED 625nm- for treatment of superficial, benign vascular and pigmented lesions. Yellow LED 590nm - treatment of periorbital wrinkles and rhytides.

	muscle tissue; and to temporarily increase local blood circulation where applied.	promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.	The infrared light (835±15nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.	

Table 2 - Performance Comparison

Device Feature	**Subject Device (K230342)**	**Predicate Device 1 (K200751)**	**Predicate Device 2 (K222751)**	**Predicate Device 3 (K200104)**
Wavelength (nm)	Red light 633nm±15nm Blue light 469nm±15nm Infrared light 835nm±15nm	Red light 630±15 Blue light 415±15 Infrared light 835±15	Red light 633nm±15nm Blue light 417nm±15nm Infrared light 835nm±15nm	Red light 625nm±5nm Blue light 465nm±5nm Yellow light 590nm±5nm
Panels Type	5 panels: 2400 EA LEDs. The panels may emit the three light (red, blue, infrared) Blue: 800EA, Red: 800EA, Infrared: 800EA	5panel: 300 EA LEDs. The panels may emit the three light (red, blue, infrared)	RBY Irradiator has 5 panels: Red light:465EA LEDs; blue light: 470EA LEDs; yellow light: 465EA LEDs; RBI irradiator: has 5 panels: Red light:465EA LEDs; blue light: 470EA LEDs; infrared: 465EA LEDs; The panels may emit the three light (red, blue infrared) individual or in	Three type, each head type has only one light. Red, Blue, yellow.

			combination	
LED power	Each LED lamp bead has 1 diodes that emit single color, the energy power of a diode is: Red light: 120mw Blue light: 160mw Infrared light: 100mw	Each LED lamp bead has 3 diodes that emit different colors, the Energy power of a diode is 3W.	Each panel has three different kinds of light-emitting diodes, and the energy power of the diode is 0.5W	Unknown
Maximum power density	Red light: 75mW/cm^2 Blue light: 35 mW/cm^2 IR: 120 mW/cm^2	Red light: 115 mW/cm^2 Blue light: 120 mW/cm^2 IR: 70 mW/cm^2	Red light: 20~96 mW/cm^2 Blue light: 10~120 mW/cm^2 Infrared: ≤ 70 mw/cm^2 Red/IR: 166mW/cm^2 Blue/IR: 190mW/cm^2	Red light: 100mW/cm^2 Blue light: 45 mW/cm^2 Yellow light: 35 mW/cm^2
Treatment area	1228 cm^2	1410 cm^2	900 cm^2±10% cm^2	500cm^2 and 860cm^2
Treatment time	20 minutes (recommended Treatment Time)	20 minutes (recommended Treatment Time)	20 minutes (recommended Treatment Time)	20 minutes (recommended Treatment Time)
Working distance	10~15cm	10~15cm	Unknown	Unknown
Power supply	AC 100-240V 50/60Hz 440VA	AC 100-240V 50/60Hz 440VA	AC 100-240V 50/60Hz	Unknown
Operation interface	Display Screen	Display Screen	Display Screen	Display Screen
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-1-2	Comply with IEC 60601-1 and IEC 60601-1-2	Comply with IEC 60601-1 and IEC 60601-1-2	Comply with IEC 60601-1 and IEC 60601-1-2
Radiation Safety	Comply with IEC 60601-2-57	Comply with IEC 60601-2-57	Comply with IEC 60601-2-57	Comply with IEC 60601-2-57
Photobiological safety	Comply with IEC 62471	Comply with IEC 62471	Comply with IEC 62471	Comply with IEC 62471

9.0 Conclusion

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