February 18, 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: K220214
Trade/Device Name: IPL System - KDT750
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: ONF
Dated: January 19, 2023
Received: January 19, 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.

510(k) Number *(if known)*
K220214

Device Name
IPL System - KDT750

Indications for Use *(Describe)*
The IPL System - KDT750 is intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialties of general and plastic surgery, and dermatology.

Indications for use for IPL System with 515-980nm IPL Handpiece (SR Handpiece).
• Benign pigmented epidermal and cutaneous lesions including warts, melasma, epithelides (freckles) and lentigines.
• Benign cutaneous vascular lesions, including port wine stains, facial and truncal telangiectasias, rosacea, erythema of rosacea and poikiloderma of Civatte.
• For use on skin types(I-V)

Indications for use for IPL System with 640-950nm IPL Handpiece (HR Handpiece).
• The removal of unwanted hair to effect stable long-term or permanent hair reduction.
• For use on Fitzpatrick skin types (I-V)

* 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.

K220214_510(k) Summary
(As required by 21 CFR 807.92)

1.0 Submitter Information

Company:	Shanghai Omni Laser Skinology Co., Ltd.
Address	Floor 3, Building 3, NO. 227, Mingqiang Road, Songjiang District, Shanghai, 201612, CHINA
Phone:	+86-021-54847192
E-mail:	avril@omni-laser.com
Contact	Avril Ouyang
Title:	General Manager

· Date of Preparation: Feb. 17, 2023

2.0 Device Information

Trade/Device Name:	IPL System
Model:	KDT750
Regulation Description:	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Device:	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Review Panel:	General & Plastic Surgery
Product Code:	ONF
Submission Type:	Traditional 510(k)
Regulation Number:	CFR 878.4810
Device Class:	Class II

3.0 Predicate Device Information

Trade/Device Name:	Alma Harmony ^{XL} Multi-Application Platform
510k Number:	K072564
Submitter:	Alma Lasers, Ltd.

4.0 Device Description

The IPL System - KDT750 is a multi-wavelength non-invasive system for IPL skin treatments, treatment of vascular and pigmented lesions, and hair removal using two wavelength ranges: 530-950nm and 640-950nm. The IPL System consists of a system console, electronics and software, cooling system, and two hand pieces with different wavelength.

5.0 Indications for Use

The IPL System - KDT750 is intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialties of general and plastic surgery, and dermatology.

Indication for use for the 530-950nm wavelength handpiece (SR Handpiece)

- Benign pigmented epidermal and cutaneous lesions including warts, melasma, epithelides (freckles) and lentigines.

- Benign cutaneous vascular lesions, including port wine stains, facial and truncal telangiectasias, rosacea, erythema of rosacea and poikiloderma of Civatte.
- For use on skin types(I-V).

Indication for use for the 640-950nm wavelength handpiece (HR Handpiece)

- The removal of unwanted hair to effect stable long-term or permanent hair reduction.
- For use on Fitzpatrick skin types (I-V).

* 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.

6.0 Comparison of Technological Characteristics with the Predicate Device

Table 1 - Comparison table of the Subject device (SR Handpiece) and Predicate device (SSR Module AFT Handpiece)

Device Feature	IPL System- SR Handpiece	Harmony^{XL}-SSR Module AFT Handpieces	Comparison
Wavelength	530-950 nm	540-950 nm	Note 1
Indications for use	The IPL System - KDT750 is intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialties of general and plastic surgery, and dermatology. • Benign pigmented epidermal and cutaneous lesions including warts, melasma, epithelides (freckles) and lentigines. • Benign cutaneous vascular lesions, including port wine stains, facial and truncal telangiectasias, rosacea, erythema of rosacea and poikiloderma of Civatte. • For use on skin types (I-V).	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology • The treatment of moderate inflammatory acne vulgaris. • The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma and ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules. • The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • Use on all skin types (Fitzpatrick I-VI).	Note 2

Light Source	Pulsed light with AFT and EDF	Pulsed light with AFT and EDF	Same
Timers	1, 3, 12 seconds	1, 3, 30 seconds	Note 3
Energy Density (Fluence)	1-12 J/cm^2	1-15 J/cm^2	Same
Spot Size	8*40 mm (3.2 cm^2)	3 cm^2	Same
Pulse Repetition Rate	2 Hz	2 Hz	Same

Table 2 - Comparison table of the Subject device (HR Handpiece) and Predicate device (HR Module AFT Handpiece, SHR Module Handpieces)

Device Feature	IPL System- HR Handpiece	Harmony^{XL}-HR Module AFT Handpiece	Harmony^{XL}-SHR Module Handpieces	Comparison
Wavelength	640-950 nm	650-950 nm	780-950 nm	Note 1
Indication for use	The IPL System - KDT750 is intended for use in aesthetic applications requiring selective photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialties of general and plastic surgery, and dermatology. • The removal of unwanted hair to effect stable long-term or permanent hair reduction. • For use on Fitzpatrick skin types (I-V). * Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialties of general and plastic surgery, and dermatology • The treatment of moderate inflammatory acnevulgaris. • The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides(freckles). • The treatment of face and body vascular and	Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology • The treatment of moderate inflammatory acne vulgaris. • The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles). • The treatment of cutaneous	Note 2

	9, and 12 months after the completion of a treatment regime.	pigmentedlesions. • The treatment of cutaneous lesions, including scars and striae. • The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias,rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • The removal of unwanted hair to effect stable long-term or permanent hair reduction. • Use on all skin types (Fitzpatrick I-VI)	lesions including warts, scars and striae. • The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema. of rosacea, angiomas and spider angiomas, poikilodermna of Civatte, leg veins and venous malformnations. • The treatment of pseudofolliculitis barbae (PFB). • The removal of unwanted hair and to effect stable long-term or permnanent hair reduction. • Use on all skin types (Fitzpatrick I-VI), including tanned skin.	
Light Source	Pulsed light with AFT and EDF	Pulsed light with AFT and EDF	Near Infrared pulsed light	Same
Timers/Pulse width	1,3 and 30 seconds	30, 40, 50 msec	1, 3 and 30 seconds	Same
Energy Density (Fluence)	1-7 J/cm^2	5-25 J/cm^2	1 – 7 J/cm^2	Note 4
Spot Size	15*50 mm (7.5 cm^2)	6.4 cm^2	3 cm^2	Note 5
Pulse Repetition Rate	3 Hz	2/3 Hz	3 Hz	Same

Difference Analysis:

Note 1 Wavelength

The wavelength range of proposed devices is very closed to predicate devices. The slight difference is considered to have no negative effect on effectiveness and safety, and the bench tests conducted on the proposed device support substantial equivalence to the predicate device.

Note 1 Indications for Use

Though the Harmony^{XL}'s handpieces has more indications than the KDT750's, the intended use of subject device is covered by the predicate device, which forms the foundation of their comparison, which will not result in negative safety and effectiveness, this forms the foundation of Substantial Equivalence.

Note 3: Timers

The proposed device (K220214, SR Handpiece) has a similar timer range as the predicate device (K072564, SSR Handpiece). The slight difference in settings do not result in negative safety and effectiveness. The bench tests conducted on the proposed device support substantial equivalence to the predicate device

Note 4: Energy Density (Fluence)

The proposed device has an energy density that is similar to the predicate device, and the differences do not result in negative safety and efficacy effects. The bench tests conducted on the proposed device support substantial equivalence to the predicate device.

Note 5: Spot Size

The proposed device has a larger spot size with the predicate device. However the differences in spot sizes are not considered to produce a negative effect on safety and safety. The bench tests conducted on the proposed device support substantial equivalence to the predicate device.

The differences noted between IPL System - KDT750 and the predicate device, Alma Harmony^{XL} Multi-Application Platform (K072564), do not present any new or different questions related to safety and effectiveness.

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)

  IEC60601-1:2005+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

  IEC 60825-1:2007, Safety of laser products - Part 1: Equipment classification and requirements.

  IEC 60601-2-57:2011, Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

- Biocompatibility

  ISO 10993-5:2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.

  ISO 10993-10:2010 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 IPL System-KDT750 is as safe and effective as its predicate devices.

The IPL System-KDT750 has the same intended use and same technological characteristics and specifications as its predicate devices. Thus, the IPL System is substantially equivalent to its predicate devices.