January 28, 2022

Shanghai Apolo Medical Technology Co., Ltd.
Felix Li
RA Supervisor
Room 301-310, Building 11, No.388, Yindu Road, Xuhui
District
Shanghai, Shanghai 200231
China

Re: K203395
Trade/Device Name: Platform treatment 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: ONF, GEX
Dated: October 21, 2021
Received: November 1, 2021

Dear Felix Li:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203395

Device Name
Platform Treatment System

Indications for Use *(Describe)*
The Platform Treatment System can be used in dermatology, cosmetic surgery, and other surgical applications according to the different hand pieces. The specific indications should reference to the indications of each hand piece.

(1) IPL Handpiece
- Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen;
- Moderate inflammatory acne vulgaris;
- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
- Cutaneous lesions including scars;
- Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations.

(2) Q-switched Nd:YAG laser Handpiece (1064nm wavelength):
- Benign vascular and pigmented lesions, age spots;
- Nevus spilus;
- Tattoo removal.

(3) Long pulsed Nd:YAG Handpiece:
- Benign vascular lesions
- Superficial and deep telangiectasias (venulectasias)
- Benign cutaneous lesions
- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles
- Laser skin resurfacing procedures
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.
- Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles.
- Removal or lightening of unwanted hair (with and without adjuvant preparation)
- Treatment of pseudofolliculitis barbae (PFB)

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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510(k) summary

I Submitter

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Date of preparation: Jan 27th, 2022.

II Proposed Device

Trade Name of Device:	Platform Treatment System
Common name:	Powered Laser Surgical Instrument
Regulation Number:	21 CFR 878.4810
Regulatory Class:	Class II
Product code:	GEX
Review Panel	General & Plastic Surgery

III Predicate Devices

510(k) Number:	K200746
Trade name:	IPL Treatment System
Common name:	Low Level Laser System for Aesthetic Use
Classification:	Class II
Product Code:	ONF
Manufacturer	Shanghai Apolo Medical Technology Co., Ltd.

510(k) Number:	K192856
Trade name:	MT One

Common name:	Powered Laser Surgical Instrument
Classification:	Class II
Product Code:	GEX, ONG, ONF, ONE
Manufacturer	M&T SRL
510(k) Number:	K072564
Trade name:	Harmony XL Multi-Application Platform and Thermoelectric Cooler
Common name:	Powered Laser Surgical Instrument
Classification:	Class II
Product Code:	GEX, FTC, HHR, LNK
Manufacturer	Alma Lasers, Ltd.

IV Device description

The proposed device, Platform Treatment System, HS-900K can be used in dermatology, cosmetic surgery, and other surgical applications according to the different hand pieces. These five handpieces are (1) Intense Pulsed Light (IPL) Handpiece, (2) Q-switched Nd:YAG laser Handpiece and (3) Long pulsed Nd:YAG Handpiece. The proposed device is provided non-sterile, and not to be sterilized by the user prior to use.

The main unit consists of:

(1) The Power supply module: Controls electrical supply to the entire system.

(2) The Control module: Controls and coordinates the various components of the system for optimum performance. It also contains the following control features:

a) Key switch: Used to turn on and off the power supply. (Clockwise to turn on and counter clockwise to turn off)

b) Emergency turn off switch: The red button found in the front panel of the machine is used to immediately shut off the machine's power supply in case of any emergency. Depressing this button will cut off the power supply to the whole system. Rotating the button in the direction of the arrow printed on its surface will disengage the button and will reengage the power supply. When this button is engaged remember to turn the key switch to the off position afterwards.

c) The touch Screen: True color TFT LCD (Liquid Crystal Display) shows the operational settings and adjustments as well as system

status is displayed on the screen.

(3) The display module: Displays various information of the system and accept users' instruction.

(4) High current capacitors: Delivers adequate electrical energy to guarantee sufficient power during operation.

(5) Cooling system: Maintains a stable thermal environment for optimum performance.

(6) Laser generator: The unit uses 110V 50/60Hz single-phase power supply. Its capability should be less than 2900W. Use a 25A (110V 50/60Hz), single-phase three-wire outlet at an international level.

V Indication for use

The Platform Treatment System can be used in dermatology, cosmetic surgery, and other surgical applications according to the different hand pieces. The specific indications should reference to the indications of each hand piece.

(1) IPL Handpiece
- Permanent hair reduction- long-term stable reduction in number of hairs re-growing after a treatment regimen;
- Moderate inflammatory acne vulgaris;
- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
- Cutaneous lesions including scars;
- Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias,
erythema of rosacea, leg veins, spider angiomas and venous malformations.

(2) Q-switched Nd:YAG laser Handpiece (1064nm wavelength):
- Benign vascular and pigmented lesions, age spots;
- Nevus spilus;
- Tattoo removal.

(3) Long pulsed Nd:YAG Handpiece:
- Benign vascular lesions
- Superficial and deep telangiectasias (venulectasias)
- Benign cutaneous lesions
- Pigmented lesions to reduce lesion size, for patients with lesions that would

potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles
- Laser skin resurfacing procedures
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.
- Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles.
- Removal or lightening of unwanted hair (with and without adjuvant preparation)
- Treatment of pseudofolliculitis barbae (PFB)

VI Comparison of technological characteristics with the predicate devices

Item	Proposed device	Predicate device (IPL Treatment System K200746)	Discussion
Indication for use	The Platform Treatment System with IPL handpiece is intended for medical use in the treatment of the following dermatologic conditions: - Permanent hair reduction - long-term stable reduction in number of hairs re-growing after a treatment regimen; - Moderate inflammatory acne vulgaris; - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles); - Cutaneous lesions including scars; - Benign cutaneous	The IPL treatment system is intended for medical use in the treatment of the following dermatologic conditions: - Permanent hair reduction - long-term stable reduction in number of hairs re-growing after a treatment regimen; - Moderate inflammatory acne vulgaris; - Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles); - Cutaneous lesions	Identical

	vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations.	including scars; - Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial truncal and leg telangiectasias, erythema of rosacea, leg veins, spider angiomas and venous malformations.	
Light source	Intense pulsed light (Xenon Flash Lamp)	Intense pulsed light (Xenon Flash Lamp)	Identical
Wavelength range	420 – 1200 nm	420 – 1200 nm	Identical
Energy output	4.1-50.8 J/cm^2	4.1-50.8 J/cm^2	Identical
Pulse width	5-20 ms	5-20 ms	Identical
Pulse duration	5-50 ms	5-50 ms	Identical
Spot size	12*35mm, 15*50mm	12*35mm, 15*50mm	Identical
Filters	420 -1200nm: Acne; 510 -1200nm: Acne, vascular, pigment; 560 -1200nm: Acne, vascular, pigment; 610-1200nm: Hair removal; 640-1200nm: Hair removal; 690-1200nm: Hair removal;	420 -1200nm: Acne; 510 -1200nm: Acne, vascular, pigment; 560 -1200nm: Acne, vascular, pigment; 610-1200nm: Hair removal; 640-1200nm: Hair removal; 690-1200nm: Hair removal;	Identical
Fluences	420 -1200nm: 4.1-50.8J/ cm^2; 510 -1200nm: 3.8-47 J/ cm^2; 560 -1200nm: 3.7-43.3 J/ cm^2;	420 -1200nm: 4.1-50.8J/ cm^2; 510 -1200nm: 3.8-47 J/ cm^2; 560 -1200nm: 3.7-43.3 J/ cm^2;	Identical

	610-1200nm: 3.5-38.7 J/ cm^2; 640-1200nm: 3.3-37.4J/ cm^2; 690-1200nm: 3.1-33.4J/ cm^2;	610-1200nm: 3.5-38.7 J/ cm^2; 640-1200nm: 3.3-37.4J/ cm^2; 690-1200nm: 3.1-33.4J/ cm^2;	
Output mode	Pulse mode	Pulse mode	Identical
Deliver materials	Direct sapphire Coupling	Direct sapphire Coupling	Identical

Item	Proposed device	Predicate device (MT ONE K192856)	Discussion
Indication for use	The Platform Treatment System with 532/1064 nm Nd:YAG Q-Switch Laser Handpiece is indicated for: • Benign vascular and pigmented lesions, age spots; • Nevus spilus; • Tattoo removal.	The MT ONE with 532/1064 nm Nd:YAG Q-Switch Laser Handpiece is indicated for: • Benign vascular and pigmented lesions, age spots; • Nevus spilus; • Tattoo removal.	Identical
Wavelength range	532/1064 nm	532/1064 nm	Identical
Energy output	Max 1.2J (532nm) Max 2.4J (1064nm)	3.2 J/cm^2 (532nm) Φ8mm 4 J/cm^2 (1064nm) Φ8mm	Equivalent
Spot size	1,2,3,4,5 mm	1,2,3,4,5,8 mm	Equivalent
Frequency	1 to 10 Hz	Up to 10 Hz	Identical
Pulse duration	< 10 ns	15 ns	
Deliver materials	Direct sapphire Coupling	Direct sapphire Coupling	Identical

Item	Proposed device	Predicate device Harmony XL Multi-application Platform K072564	Discussion
Indication for use	The Platform Treatment System with 1064 nm Long Pulse Nd:YAG Laser Handpiece is indicated for: • Benign vascular lesions • Superficial and deep telangiectasias (venulectasias) • Benign cutaneous lesions • Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. • The non-ablative treatment of facial wrinkles • Laser skin resurfacing procedures • Reduction of red pigmentation in hypertrophic and	The 1064 nm Nd:YAG Laser Module handpieces (Long Pulsed and Q-Switched with and without contact-cooling) are indicated for treatment and clearance of. • Benign vascular lesions such as, but not limited to treatment of: ➢ Port wine stains ➢ Hemangiomas ➢ Warts • Superficial and deep telangiectasias (venulectasias) ➢ Reticular veins (0.1-4.0 mm dia.) of the leg ➢ Rosacea ➢ Venus lake ➢ Leg veins ➢ Spider veins ➢ Poikiloderma of Civatte ➢ Angiomas • Benign cutaneous lesions, such as, but not limited to: ➢ Warts ➢ Scars	Identical

	keloid scars where vascularity is an integral part of the scar. • Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. • Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles. • Removal or lightening of unwanted hair (with and without adjuvant preparation) • Treatment of pseudofolliculitis barbae (PFB)	➢ Striae ➢ Psoriasis ➢ Solar lentigos (sun spots) ➢ Cafd-au-lait macules ➢ Seborrheic keratoses ➢ Nevi and nevus of Ota ➢ Chloasma ➢ Verrucae ➢ Skin tags ➢ Keratoses ➢ The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos). ➢ Plaques • Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. • The non-ablative treatment of facial wrinkles, such as, but not limited to: ➢ Periocular wrinkles ➢ Perioral wrinkles	

		• Laser skin resurfacing procedures for the treatment of: ➢ Acne scars ➢ Wrinkles • Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. • Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. The 1064 nm Nd:YAG lasers (Long Pulsed only, with and without contact-cooling) is indicated for: • Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles. • Removal or lightening of unwanted hair (with and without adjuvant preparation) • Treatment of pseudofolliculitis barbae (PFB)	

Wavelength range	1064 nm	1064 nm	Identical
Fluence	10 ~ 500 J/ cm^2	Up to 30 ~ 450J/ cm^2	Equivalent
Spot size	2.2x5mm, ¢6mm, ¢9mm	2,6,10mm	Equivalent
Frequency	1 Hz	1 Hz	Equivalent
Pulse duration	10 ~ 40ms	10, 12, 15, 45ms	Equivalent
Deliver materials	Aluminum alloy	Aluminum alloy	Identical

VII Non-Clinical Testing

A series of tests have been performed to verity that the proposed device met all design specification. The test result demonstrated that the proposed device complies with the following standards:

Electrical safety and electromagnetic compatibility

- IEC 60601-1: 2005+corr.1:2006+Corr.2.2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and requirements
- IEC 60601-2-22:2007(third edition)+A1:2012 for use in conjunction with IEC 60601-1:2005 (third edition)+A1:2012 Medical electrical equipment - Part 2-22: Particular requirements for the safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- 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

VIII Clinical Testing

It is not applicable.

IX Concl usion

Based on the performance testing and validation studies that the subject device is substantially equivalent to the predicate device.