April 17, 2020

Shanghai Apolo Medical Technology Co., Ltd.
Ms. Claire Zhang
Manager
Shanghai Landlink Medical Information Technology Co., Ltd.
Room 703, 705, Building 1, West Guangzhong Road 555, Jingan District
Shanghai, 200071 CN

Re: K200118
Trade/Device Name: Diode Laser Therapy Device
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: January 15, 2020
Received: January 21, 2020

Dear Claire Zhang:

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,

Colin Kejing Chen
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K200118

Device Name
Diode Laser Therapy Devices

Indications for Use *(Describe)*
The Diode Laser Therapy Device is indicated for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. It is suitable for all skin types (Fitzpatrick skin type I-VI), including tanned skin.

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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K200118-510(k) summary

I Submitter

Shanghai Apolo Medical Technology Co., Ltd.
4F, Building A, No.388, Yindu Road, Xuhui District, Shanghai 200231, China
Preparation Date: Apr.16, 2020

Establishment Registration Number: 3007120647

Contact person: Felix Li
Position: Regulatory Affairs
Phone: +86-138 4919 0618
Fax: +86-21-34622840
E-mail: liqiang@apolo.com.cn

II Proposed Device

Trade Name of Device:	Diode Laser Therapy Device
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:	K172193
Trade name:	Modified Alma Lasers Soprano XL™Family of Multi-Application and Multi-Technology Platforms [SopranoXL, SopranoXLi, Soprano ICE and Soprano ICE Platinum] with Trio Diode LaserModule
Common name:	Powered Laser Surgical Instrument
Classification:	Class II
Product Code:	GEX
Manufacturer	Alma Lasers Inc.

IV Device description

The Diode Laser Therapy Devices is designed to be used in dermatological practice for stable, long term hair reduction. The principle of laser hair removal is selective

photothermolysis. The wavelength of 810nm, 755, and 1064nm would be able to effectively penetrate deep into and absorbed by the target chromophore. The laser power is delivered to the treatment region via a delivery system.

The proposed device includes power supply system, delivery system, control system, cooling system, laser system.

The 755nm, 810nm, 1064nm handpieces with different treatment size are available for different models.

V Indication for use

The Diode Laser Therapy Device is indicated for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. It is suitable for all skin types (Fitzpatrick skin type I-VI), including tanned skin.

VI Comparison of technological characteristics with the predicate devices

Item	Proposed device	Predicate device (K172193)
Product name	Diode Laser Therapy Device	Modified Alma Lasers Soprano XL™Family of Multi-Application and Multi-Technology Platforms [SopranoXL, SopranoXLi, Soprano ICE and Soprano ICE Platinum] with Trio Diode LaserModule
Product Code	GEX	GEX
Regulation No.	21 CFR 878.4810	21 CFR 878.4810
Class	Class II	Class II
Indication for use	The Diode Laser Therapy Device is indicated for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. It is suitable for all skin types (Fitzpatrick skin	Intended use: The device is intended for use in dermatologic and general surgical procedures. Indication for use:

	type I-VI), including tanned skin.	The Soprano trio Diode Laser Module is intended for use in dermatology procedures requiring coagulation. The indications for use for the Soprano Trio Diode Laser Module include: • Benign vascular and vascular dependent lesions removal. The indications for use for the Soprano 1064nm Diode Laser Module include: • The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. • Treatment of Pseudo folliculitis Barbae (PFB) • Use on all skin types (Fitzpatrick I-VI), including tanned skin.

		The indications for use for the 810nm Modified Diode Laser Module 1.2cm^2 include: • The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. • The treatment of benign vascular and pigmented lesions.(The Laser Blanch (LB) Mode) • Use on all skin types (Fitzpatrick I-VI), including tanned skin. (HR, SHR and LB Modes) Optional Tapered Light Guide: It is intended for the same use as the device. The indications for use for the 810nm Modified Diode Laser Module 2 cm^2 include:

		• The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen. • Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, and SHR Modes) The indications for use for the 755nm Diode Laser Module include: • The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a

		treatment regimen. • The treatment of benign vascular and pigmented lesions.(The Laser Blanch Mode) • Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, SHR and Laser Blanch Modes) NIR Modules The Alma Lasers NIR Modules intended use is to emit energy in the near infrared (NIR) spectrum to provide topical heating. The indications for use for NIR Modules are: • Elevating the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness, • The temporary relief of minor joint pain associated with arthritis, • The temporary increase in local circulation where applied, and The relaxation of muscles; may also help muscle spasms, minor

					sprains and strains, and minor muscular back pain.
Laser Type	Solid state				Solid state
Light Delivery system	755nm handpiece 810nm handpiece 1064nm handpiece				755nm module 810nm module 1064nm module Soprano trio diode laser module NIR Modules
Handpiece tip material	Sapphire				Sapphire
Controls	Footswitch or handpiece				Footswitch or handpiece
Handpiece Spot size	HS-810N & 811N	HS-812N	HS-816 & 818	HS-817 & 819	Soptano titanium
	12x18mm; 12x30 mm;	12x20mm; 15x40 mm;	12x14mm; 10x10 mm	12x16mm; 12x20 mm	ALEX 755nm handpiece: 15 x10mm; Speed 810nm handpiece 20 x10mm Trio handpiece:2cm^2.
Energy density	1~110J/cm^2	1~62J/cm^2 1~40 J/cm^2	1~72J/cm^2 1~60J/cm^2	1~62J/cm^2 1~64 J/cm^2	120J/ cm^2, 150J/cm^2 (optional).
Pulse width	10-400ms	10-300ms; 1-200ms.	1-200ms; 1-100ms	10-300 ms	810,755nm: 3.3~200; 1064nm: 3.3~280 Trio:40-800ms
Pulse frequency	1, 2, 3, 5, 8，10HZ.	1,2,3,5,8，10,15HZ	1,2,3,5,8,10,15 Hz	1,2,3,5,8,10Hz	810,755nm: 0.5~3 Hz (HR), 5~10 Hz(SHR); 2 Hz(LB) 1064nm: 0.5~3 Hz (HR), 5~10 (SHR) Trio:40-800ms,Up to 10Hz.
Wavelen	755nm/810nm/1064nm for option				755nm/810nm/1064nm

gth		and three in one for option
Operation interface	LCD color Touchscreen	LCD color Touchscreen
Laser classification	Class IV	Class IV
Software	Yes	Yes

The indication of proposed device is covered by the predicated device. The proposed device is only intended to use for hair removal. The device includes seven models for clearance in this submission. The differences between models are the treatment area, laser energy density, pulse frequency, pulse width. These are covered by the predicated device. The different wavelengths (755nm/810nm/1064nm) are available for all models. The proposed device does not have NIR Modules or Trio Diode Laser modules (combining wavelengths) compared to the predicate device. The minor differences in indication do not alter the use of the proposed device.

VII Non-Clinical Testing

A battery of tests has been performed to verify 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

Biocompatibility

The patient contact component of the device was performed the Biocompatibility

testing and reference standards as following testing:

- Cytotoxicity
  ISO 10993-5:2009, Biocompatibility Evaluation of Medical Device - Part 5: Tests for In Vitro Cytotoxicity
- Sensitization ISO 10993-10:2010,
  Biocompatibility Evaluation of Medical Device - Part 10: Tests for Irritation and Shin Sensitization.
- Irritation
  ISO 10993-10:2010, Biocompatibility Evaluation of Medical Device - Part 10: Tests for Irritation and Shin Sensitization.

VIII Clinical Testing

It is not applicable.

Ⅸ Conclusion

The performance testing and software validation testing determined that the subject device is substantially equivalent to the predicate device.