May 28, 2020

Shanghai Apolo Medical Technology Co., Ltd.
℅ 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: K200116
Trade/Device Name: PicoSecond Nd: YAG Laser 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: GEX
Dated: April 16, 2020
Received: April 27, 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

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Sincerely,

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Acting Assistant Director
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and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

K200116-510(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. 09, 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:	PicoSecond Nd: YAG Laser 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:	K191685
Trade name:	PicoWay Laser System
Common name:	Laser Surgical Instrument
Classification:	Class II
Product Code:	GEX
Manufacturer	Candela Corporation

510(k) Number:	K173700
Trade name:	Picoplus laser system
Common name:	Laser Surgical Instrument
Classification:	Class II
Product Code:	GEX

Manufacturer Lutronic Corporation

IV Device description

The PicoSecond Nd: YAG Laser System is a Nd: YAG solid state laser, which can deliver the energy at picosecond pulse bursts to the skin. The system is composed of laser generator, articulated arm, handpence, laser power supply, cooling system, display and control system.

The PicoSecond Nd: YAG Laser System produces a pulsed beam of coherent near infrared (1064nm) and visible (532nm) light. This beam is directed to the treatment zone by means of an articulated arm coupled to a handpiece. The outputs of the two lasers are designed to be co-linear on the laser rail so that their beam paths are identical as they exit the laser system.

V Indication for use

Indication for use

The PicoSecond Nd: YAG Laser System is intended for use in surgical and aesthetic application in the medical dermatology and general and plastic surgery as follows:

1064nm wavelength:

- Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple.
- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.

532nm wavelength:

- Removal of tattoos on Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange.
- Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.

VI Comparison of technological characteristics with the predicate devices

A table comparing the key features of the proposed and predicate devices is provided below.

Item	**Subject device**	**Predicate device (K191685)**	**Predicate device (K173700)**
Product name	PicoSecond Nd: YAG Laser System	PicoWay Laser System	Picoplus laser system
Product Code	**GEX**	**GEX**	GEX

Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Class	Class II	Class II	Class II
Indication for use	The PicoSecond Nd: YAG Laser System is intended for use in surgical and aesthetic application in the medical dermatology and general and plastic surgery as follows: 1064nm wavelength: • Removal of tattoos on all skin type (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple. • Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV. 532nm wavelength: • Removal of tattoos on	The PicoWay laser system is indicated for the following at the specified wavelength 532 nm: Removal of tattoos for Fitzpatrick skin types I - III to treat the following tattoo colors: red, yellow and orange. 730 nm: Removal of tattoos for Fitzpatrick skin types II - IV to treat the following tattoo colors: green and blue. 785 nm: Removal of tattoos for Fitzpatrick skin types II - IV to treat the following tattoo colors: green and blue. 1064 nm: Removal of tattoos for all skin types (Fitzpatrick I - VI) to treat the following tattoo colors: black, brown, green, blue and purple. The Picoway laser system is also indicated for benign pigmented lesions	The Picoplus Laser system is indication for use in surgical and aesthetic application in the medical specialties of dermatology and general and plastic surgery as follows: The 532 nm wavelength and 450 pico-second pulse duration of the PICOPLUS system is indicated for • Removal of tattoos for Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange. • Treatment of benign pigmented lesions removal for Fitzpatrick Skin Types I-IV. The 1064 nm wavelength and 450 pico-second pulse duration of the PICOPLUS system is indicated for:

	Fitzpatrick skin types I-III with the following tattoo colors: red, yellow and orange. • Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV.	removal for Fitzpatrick Skin Types I - IV. The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II - V. The Resolve handpieces (532 nm HE, 532nm, 1064nm) are also indicated for treatment of wrinkles in Fitzpatrick Skin Types I - IV The Resolve Fusion handpiece (1064 nm) is indicated for the treatment of wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I - IV The Resolve Fusion handpiece (532 nm) is indicated for the treatment of benign pigmented lesions in Fitzpatrick Skin Types I - IV.	• Removal of tattoos on all skin types (Fitzpatrick skin types I-VI) with the following tattoo colors: black, brown, green, blue and purple. • Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV. The 1064 nm wavelength and nanosecond pulse duration of the PICOPLUS system is indicated for: • Treatment of benign pigmented lesions on Fitzpatrick skin types I-VI • Removal of dark and mult i-colored tattoos containing dark colored tattoo inks on Fitzpatrick skin types I-VI The 532 nm

			wavelength and nanosecond pulse duration of the PICOPLUS system is indicated for: • Treatment of benign pigmented lesions on Fitzpatrick skin types I-IV • Removal of lighter colored tattoo inks, including red and yellow inks, on Fitzpatrick skin types I-III
Anatomical site	Skin and subcutaneous tissue	Skin and subcutaneous tissue	
Technology	The PicoSecond Nd: YAG Laser System produces a pulsed beam of coherent near infrared (1064nm) and visible (532nm) light. It can crush lesions tissue efficient by instantaneous emit laser energy, 1064 & 532nm wavelength act on the target tissue in a short time (300-500ps). The outputs of the two lasers are designed	The PicoWay Laser System is a solid‐state laser capable of delivering energy at wavelengths of 1064 nm, 532 nm, 730 nm or 785 nm at extremely short duration in the range of 240‐500 ps. The 1064 nm wavelength can be frequency‐doubled to 532 nm as desired. The outputs of the two lasers are designed to be co‐	The PICOPLUS Laser System is a laser system, delivering energy at wavelengths of 1064 nm and 532 nm, both at pulse durations of 450 picoseconds (ps) and 2 nanoseconds (ns). The laser system is comprised of a system console, an articulated arm and attached handpieces.

	to be co‑linear on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either the 532 nm or 1064 nm wavelengths.		linear on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either the 532 nm or 1064 nm wavelengths.			
Wavelength (nm)	1064nm	532nm	1064nm	532nm	1064nm	532nm
Maximum pulse energy	500mJ	250mJ	400mJ	200mJ	800mJ (picosecond)	300mJ (picosecond)
Pulse duration	300 – 500 ps		240-500ps		450ps	
Repetition rate	Single, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Hz		Single, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Hz		N/A	
Spot size	Adjustable spot size 2~10mm		2, 3, 4, 5, 6, 7, 8, 9, 10 mm		1064nm Handpiece 1 (450ps): 3, 5, 4 6mm Handpiece 2: 6, 7, 8, 9, 10mm 532nm Handpiece 1 (450ps): 3.3, 4.3, 5.3mm Handpiece 2: 4.3, 5.3, 6.5, 8mm	
Beam delivery	Articulated arm light guide		Articulated arm light guide		Articulated arm light guide	
Handpiece	Zoom handpiece (532nm, 1064 nm)		Resolve handpieces (532 nm HE, 532nm, 1064nm); The Resolve Fusion handpiece (532nm,		Handpiece 1, 2 (450ps) (1064nm, 532nm) Handpiece1, 2 (2ns) (1064nm, 532nm)	

		1064 nm); Zoom handpiece (532nm, 1064 nm).	
System dimension	97cm H x 48cm W x 97cm D	107 cm H x 46 cm W x 69 cm D	unknown
System weight	130kg	125kg	unknown
Electrical requirements	120VAC 10A, 50/60Hz	200-240 VAC, 50/60 Hz, 30 A, 4600 VA single	unknown

The indication of the proposed device is covered by the predicate. The maximum pulse energy of the proposed device is higher than the K191683, and lower than the K113700 predicate device. It can be considered that the propose device can achieve its intended use and is safety. The handpiece types of proposed device are less than the predicate devices. This difference does not affect the safety and effective of proposed device.

VII Non-Clinical Testing

A battery of tests was 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 60601-2-22:2007+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 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and requirements

VIII Clinical Testing

It is not applicable.

Ⅸ Conclusion

The proposed device, PicoSecond Nd: YAG Laser System has the same the

intended use as the predicate device. It presents similar technological characteristics as the predicate device including the laser type, wavelengths, device design, pulse width, frequency, spot sizes. The non-clinical testing determined that the subject device is substantially equivalent to the predicate device.