Rohrer Aesthetics, LLC
Mark Rohrer
President
105 Citation Court
Homewood, Alabama 35209

Re: K192583
Trade/Device Name: PicoLazer 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: December 17, 2019
Received: December 18, 2019

Dear Mark Rohrer:

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,

Jessica Mavadia-Shukla
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)*
K192583

Device Name

PicoLazer

Indications for Use *(Describe)*
The PicoLazer laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

1064 nm
The 1064 nm wavelength of the PicoLazer laser system is indicated for:
• treatment of benign pigmented lesions on patients with all skin types (Fitzpatrick I-VI)
• tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI)

532 nm
The 532 nm wavelength of the PicoLazer laser system is indicated for:
• treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III
• tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III

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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510(K) Summary
PicoLazer Multi-wavelength Laser
K192583

This 510(K) Summary of safety and effectiveness for the PicoLazer Multi-wavelength Laser is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Rohrer Aesthetics, LLC
Address:	Rohrer Aesthetics, LLC 105 Citation Court Birmingham, AL 35209
Contact Person:	Mr. Mark Rohrer
Telephone:	205-356-1172 – phone mrohrer@rohreraesthetics.com
Preparation Date:	September 15, 2019
Device Trade Name:	PicoLazer Laser System
Common Name:	Surgical Powered Lasers and Delivery Devices/Hand piece Accessories
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and dermatology
Regulation Number:	21 CFR 878.4810 (Product Code: GEX)
Legally Marketed Predicate Device1:	PicoCare Family manufactured by Won Tech Co Ltd
510(K) number:	K181272
Legally Marketed Predicate Device 2:	PicoWay Laser System manufactured by Syneron Candela Corporation
510(K) number:	K170597
Regulatory Class:	Class II Prescription Use
Description of the PicoLazer Multi-wavelength Laser:	The Rohrer Aesthetics, LLC PicoLazer™ laser system is a dual-wavelength (532 and 1064 nm) Nd:YAG laser system that offers a 450-picosecond pulse duration that produces a maximum energy of 500mJ at 1064nm and 250mJ at 532nm. The PicoLazer laser system consists of a system console, an articulated arm, a laser handpiece, a footswitch, and a remote interlock plug. Other components necessary for operation, such as power cables, are also included.

Indication for Use:

The PicoLazer system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

1064nm:
The 1064nm wavelength of the PicoLazer laser system is indicated for:

- treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-VI.
- tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI)

532nm:
The 532nm wavelength of the PicoLazer laser system is indicated for:

- treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III
- tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III

Performance Data:

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

IEC 60601-1 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance;

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

IEC 60601-2-22 Medical Electrical Equipment-Part 2-22: Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser Equipment

IEC 60825-1 Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

Results of Clinical Study:

A human clinical study was not required as the device is substantially equivalent to the predicate devices.

Technical Specification Comparison:

Characteristic	PicoLazer (K192583)		PicoWay Laser System (K170597)		PicoCare Family (K181272)	
Wavelength (nm)	1064nm	532nm	1064nm	532nm	1064nm	532nm
Laser Type	Nd:YAG		Nd:YAG		Nd:YAG	
Max Energy (mJ)	500mJ	250mJ	800mJ	300mJ	600mJ	300mJ
Peak Power	1.3GW	0.8GW	0.9GW	0.53GW	1.33GW	0.8GW
Spot Size	Max 10mm		Max 10mm		Max 10mm	
Pulse Duration	450ps	375ps	450ps	375ps	450ps	
Pulse Repetition rate (Hz)	1~10Hz		1~10Hz		1~10Hz	

Physical Specification:

aracteristic	PicoLazer (K192583)	PicoWay Laser System (K170597)	PicoCare Family (K181272)
Console Weight	176lbs	275lbs	198lbs
Console Size	25(W)x26(D)x48(H)in	18(W)x27(D)x42(H)in	18(W)37(D)x36(H)in
Voltage, Current	100-120 VAC, 20 A 200-240 VAC, 15 A	200-240 VAC, 30A	100-120 VAC, 20 A 220-230 VAC, 15 A
Frequency	50/60Hz	50/60Hz	50/60Hz

Indication for Use Comparison:

	PicoLazer (K192583)	PicoWay Laser System (K170597)	PicoCare Family (K181272)
1064nm Laser	Treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-VI Tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI)	Treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-IV Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following colors: black, brown, green, blue, and purple.	Tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI)
532nm Laser	Treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III Tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III	Treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-IV Removal of tattoos for Fitzpatrick skin types I-III to treat the following colors: red, yellow, and orange.	Tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III

Conclusion:	The PicoLaser Laser System's intended use, indications for use and technical specifications are substantially equivalent to the PicoWay Laser System and the PicoCare Family of Lasers.