April 11, 2024

Rhein Laser Technologies Co., Ltd.
Na Wu
Quality Manager
801,8F, E2Building, Future City, No.999 High-Tech Avenue
East Lake High-Tech Development Zone
Wuhan, 430206
China

Re: K233757
Trade/Device Name: TitanPico Laser Workstation (PICO-450)
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: November 24, 2023
Received: November 24, 2023

Dear Na Wu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.04.11 14:40:00 -04'00'

Mark Trumbore, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233757

Device Name
TitanPico Laser Workstation (PICO-450)

Indications for Use *(Describe)*
The TitanPico Laser Workstation is indicated for the following at the specified wavelength:
532nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.
1064nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors:
black, brown, green, blue and purple.
The TitanPico Laser Workstation is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.

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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Section 5 - 510(k) Summary

K233757

Date of Modification: April 10, 2024

1. Submitter's Identifications

Submitter's Name: Rhein Laser Technologies Co., Ltd.
Address: 801,8F, E2 Building, Future City, No.999 High-Tech Avenue, East Lake High-Tech Development Zone, Wuhan 430206, China(Free Trade Zone Wuhan Area)
Contact Person: Na Wu
Contact Title: Quality Manager
Contact Email Address: na.wu@lotuxs.com
Telephone: +86-027-65279157

2. Correspondent's Identifications

Correspondent's Name: Rhein Laser Technologies Co., Ltd.
Address: 801,8F, E2 Building, Future City, No.999 High-Tech Avenue, East Lake High-Tech Development Zone, Wuhan 430206, China (Free Trade Zone Wuhan Area)
ZIP Code: 430206
Contact Person: Na Wu
Contact Title: Quality Manager
Contact E-mail Address: na.wu@lotuxs.com
Telephone: +86-027-65279157

3. Name of the Device

Device Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Trade Name: TitanPico Laser Workstation
Model: PICO-450
Classification Panel: General & Plastic Surgery
Product Code: GEX
Regulation Number: 21 CFR 878.4810
Device Classification: Class II

4. The Predicate Devices

Primary Predicate device: K153527 PicoWay Laser System; K220853 PicoWay Laser System

5. Device Description

TitanPico Laser Workstation is a laser system that delivers energy in the 532nm and1064nm wavelength. The combination of wavelength, pulse duration and energy fluence are disrupting the tattoo dye or pigment particles under the skin without harming the surrounding tissue. The fragmented dye or pigment particles eventually surface and fade as the epidermal layer of the skin is renewed.

6. Intended Use of Device

The TitanPico Laser Workstation is indicated for the following at the specified wavelength:
532nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.
1064nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.
The TitanPico Laser Workstation is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.

7. Summary of Substantial Equivalence

Table 1

	Proposed device	Primary Predicate	Secondary Predicate	Comparison
510k Number	K233757	K153527	K220853	------
Product Code	GEX	GEX	GEX	Same
Proprietary Name	TitanPico Laser Workstation	PicoWay Laser System	PicoWay Laser System	------
Model	PICO-450	/	/	------
Manufacturer	Rhein Laser Technologies Co., Ltd.	SYNERON CANDELA CORPORATION	Danielle Gibboney	------
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Class	Class II	Class II	Class II	Same
Indications for use	The TitanPico Laser Workstation is indicated for the following at the specified wavelength: 532nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. 1064nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and	The PicoWay Laser System is indicated for the following at the specified wavelength: 532nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange. 1064nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and	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 I-IV to treat the following tattoo colors: green and blue.	Same

	purple. The TitanPico Laser Workstation is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.	purple. The PicoWay Laser System is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.	***785*** nm: Removal of tattoos for Fitzpatrick Skin Types II-IV to treat the following tattoo colors: green and blue. 1064 rm: Removal of tattoos for all Fitzpatrick Skin Types to treat the following tattoo colors: black, brown, green, blue and purple. The PicoWay laser system is also indicated for benign pigmented lesions 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 11-V and for treatment of Melasma for Fitzpatrick Skin Types I-IV. The Resolve handpieces ***(532*** nm **HE,** ***532*** rm, and 1064 nm) are also indicated for the treatment of wrinkles in Fitzpatrick Skin Types I-IV. The Resolve Fusion handpiece	

			(532 nm) is indicated for benign pigmented lesions removal for Fitzpatrick Skin Types **IIV.** The PicoWay laser system is indicated for the following at the specified wavelengths: ***532*** nm: Treatment of Melasma for Fitzpatrick Skin Types I-IV. Treatment of caf6 au lait macules (CALMs) for Fitzpatrick Skin Types I-IV. Treatment of Lentigines for Fitzpatrick Skin Types **I-IV.** **730** nm: Treatment of Lentigines for Fitzpatrick Skin Types I-IV. 1064 nm: Treatment of Melasma for Fitzpatrick Skin Types I-IV. Treatment of Nevus of Ota for Fitzpatrick Skin Types III-IV.	
Type of Use	Prescription Use	Prescription Use	Prescription Use	Same
Wavelength	1064/532 nm	1064/532 nm	1064/785/730/532 nm	Same
Maximum Energy	400mJ(1064nm)	450mJ(1064nm)	Unknown	Similar

	200mJ (532nm)	220mJ (532nm)		The maximum energy of the proposed device is similar to the predicate device, so this definition does not affect the safety and effectiveness.
Aiming Beam	635nm	635nm	635nm	Same
Repetition Rate	1-10Hz	1~10Hz	1~10Hz	Same
Spot size	Φ2-10mm	Φ 2mm-10mm	Φ 2mm-10mm	Same
Maximum Average Fluence (J/cm²)	6.25 J/cm²	5.7 J/cm²(1064nm) 3.2 J/cm²(532nm)	6.25 J/cm²	Same The maximum average fluence of the submitted device is the same as the predicate device K220853.
Pulse Duration	375-450ps	240-750ps	240-500 ps	Same
Laser Type	Nd: YAG	Nd: YAG	Nd: YAG	Same

Activation	Foot-switch	Foot-switch	Foot-switch	Same
User Interface	Touchscreen with GUI	Touchscreen with GUI	Touchscreen with GUI	Same
Warm Up Time	2 minutes	2 minutes	2 minutes	Same
Cooling method	Water cooling	Water cooling	Water cooling	Same
Electrical Power	~110V , 60Hz	100 - 240 VAC, 50/60 Hz,	200-240 VAC, 50/60 HZ, 4600 VA single	Different The electrical power of the proposed device is different from the subject predicate K153527. The proposed device has passed safety testing. This difference will not improve the safety and effectiveness of the proposed device.
Delivery System	Articulated arm with 2 wavelength Zoom handpiece	Articulated arm with 2 wavelength Zoom handpiece	Articulated arm with 4 wavelength Zoom handpiece	Same
System dimension	1035mm×805mm×380mm	42" H x 18” W x 27” D / 107 cm H x 46 cm W x 69 cm D		Different The system dimension of the

			Unknown	proposed device is different from the subject predicate K153527. The proposed device has passed safety testing. This difference will not improve the safety and effectiveness of the proposed device.
Software	Yes	Yes	Yes	Same
Delivery Devices (How supplied)	Non -Sterile. reusable. cleanable	Non -Sterile. reusable. cleanable	Non -Sterile. reusable. cleanable	Same
Electromagnetic compatibility and electrical safefy compliance	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	Same
Discussion for Substantially Equivalent (SE)	The proposed device TitanPico Laser Workstation products has the same purpose as the predicate device: product code, Regulation No., Class , Controls, indications for use, Type of Use, wavelength, Maximum Energy, Aiming Beam , Repetition Rate, Spot size, Maximum Average Fluence, Laser Type, Activation, User Interface, Warm Up Time, Cooling method, Delivery System, Software, delivery devices and Electromagnetic compatibility and electrical safefy compliance. The difference only exists in such contents: Electrical Power and System dimension. These items can be controlled within the scope of application. These small differences between the proposed devices and predicate devices do not cause new safety and effectiveness problems. According to the non clinical test results, the proposed device is as safe, effective and has good			

	performance as the predicate device. So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.

8. Non-Clinical Tests Submitted:

Software verification and validation was performed, and it was demonstrated that the software performs as intended according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Testing confirmed that the power output meets specification. Electromagnetic compatibility and electrical safety testing was performed per standards IEC 60601-1 Edition 3.2 2020-08 （Medical electrical equipment - Part 1: General requirements for basic safety and essential performance）, IEC 60601-1-2 Edition 4.0 2014-02 （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 Edition 3.1 2012-10 （Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical cosmetic therapeutic and diagnostic laser equipment）and IEC 60825-1:2014 (Third Edition)Safety of laser products - Part 1: Equipment classification and requirements [Including: Technical Corrigendum 1 (2008) Interpretation Sheet 1 (2007) Interpretation Sheet 2 (2007)]. Results confirmed the device meets the standards.
All patient contacting materials were assessed as per ISO10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, ISO10993-10 Fourth edition 2021-11：Biological evaluation of medical devices - Part 10: Tests for skin sensitization, ISO10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation, ISO10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity and found to be biocompatible.

9. Clinical Tests Submitted:

Summary of Substantial Equivalence" submitted of the proposed device, the proposed device series products is Substantially Equivalent (SE) to the predicate device, includes: Product code, Regulation No., Class , Controls, indications for use, Type of Use, wavelength, Maximum Energy, Aiming Beam , Repetition Rate, Spot size, Maximum Average Fluence , Laser Type, Activation, User Interface, Warm Up Time, Cooling method, Delivery System, Software, delivery devices and Electromagnetic compatibility and electrical safefy compliance. the non-clinical tests complied with the requirements of relevant recognized standards, and passed the bench tests (such as performance tests, storage condition tests), so Rhein belives that the proposed device TitanPico Laser Workstation products does not need to carry out clinical tests, and the clinical study data that have been the legally marketed device can be used for reference.

10. Conclusions drawn from clinical and non-clinical tests submitted:

Rhein believes that TitanPico Laser Workstation products is substantially equivalent to its predicate devices with same indications for use, similar technological characteristics. The non-clinical data for TitanPico Laser Workstation products supports the safety of the device and the biocompatibility, hardware and software

verification and validation demonstrate that the TitanPico Laser Workstation products should perform as intended in the specified use conditions.

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