July 30, 2023

Lotuxs Medtech (Suzhou) Co., Ltd.
Na Wu
Quality Manager
Room301,303,304, Building6,
Northwest Area of Nanopolis Suzhou,No.99 Jinjihu Avenue
Suzhou Industrial Park, Suzhou, Jiangsu 215123
China

Re: K222862
Trade/Device Name: SILKPRO Titanium Diode Laser System SILKPRO-S20S-TWC
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: June 30, 2023
Received: June 30, 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 (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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222862

Device Name
SILKPRO Titanium Diode Laser System

Indications for Use *(Describe)*
The indications for use for the SILKPRO-S20S-TWC include:
The Super Hair Removal (SHR) Mode are intended for temporary hair reduction.
The indications for use for the SILKPRO-S20S-755A 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 L-VI), including tanned skin.(HR. SHR Modes)
The indications for use for the SILKPRO-S20S-810B 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 airs 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)

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

K222862
Date of Summary Preparation: September 15, 2022
Date of Modification: July 29, 2023

1. Submitter's Identifications

Submitter's Name: Lotuxs Medtech (Suzhou) Co., Ltd.
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Contact Email Address: na.wu@lotuxs.com
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2. Correspondent's Identifications

Correspondent's Name: Lotuxs Medtech (Suzhou) Co., Ltd.
Address: Room301,303,304, Building6, Northwest Area of Nanopolis Suzhou, No.99 Jinjihu Avenue, Suzhou Industrial Park, Suzhou 215123, China
ZIP Code: 215123
Contact Person: Na Wu
Contact Title: Quality Manager
Contact E-mail Address: na.wu@lotuxs.com
Telephone: +86-0512-62880553

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: SILKPRO Titanium Diode Laser System
Model: SILKPRO-S20S-TWC, SILKPRO-S20S-755A, SILKPRO-S20S-810B.
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: K222064 Soprano Titanium

5. Device Description

The working principle of SILKPRO Titanium Diode Laser System is selective

photothermal effect. It uses its unique long pulse width laser to penetrate the epidermis to the hair follicle. The energy of the laser is preferentially absorbed by the melanin in the hair, so that the hair follicle produces high heat. Thereby destroying the structure of the hair follicle, making the hair lose the ability to regenerate, and achieving the purpose of hair removal. The treatment head adopts a uniquely designed sapphire dynamic cooling device.

SILKPRO Titanium Diode Laser System is a sophisticated high-tech laser equipment. The machine includes water cooling system. Water flows through the pipes in the handpiece to dissipate heat for the light source and the TEC water cooling block , which is used to cool the skin tissue during treatment.

6. Intended Use of Device

The indications for use for the SILKPRO-S20S-TWC include:

The Super Hair Removal (SHR) Mode are intended for temporary hair reduction.

The indications for use for the SILKPRO-S20S-755A 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 L-VI), including tanned skin.(HR. SHR Modes)

The indications for use for the SILKPRO-S20S-810B 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 airs 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)

7. Summary of Substantial Equivalence

Table 1

	Proposed device	Primary predicate device	Comparison
510k Number	K222862	K222064	------
Product Code	GEX	GEX, ILY	Same
Proprietary Name	SILKPRO Titanium Diode Laser System	Soprano Titanium	------
Model	SILKPRO-S20S-TWC, SILKPRO-S20S-755A, SILKPRO-S20S-810B,	/	------
Manufacturer	Lotuxs Medtech (Suzhou) Co., Ltd.	Alma Lasers Inc.	------
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	Same
Regulatory Class	Class II	Class II	Same
Controls	Footswitch or handpiece	Footswitch or handpiece	Same
Indications for use	The indications for use for the SILKPRO-S20S-TWC include: The super hair removal (SHR) Mode are intended for temporary hair reduction. The indications for use for the SILKPRO-S20S-755A include: The hair removal (HR) and super hair removal (SHR) Mode are intended for permanent reduction in hair regrowth	The Soprano Titanium diode laser module is intended for use in dermatology procedures requiring coagulation. The indications for use for the Soprano Trio diode laser module include: The Super Hair Removal (SHR) Mode is intended for temporary hair reduction. The Soprano Trio diode laser module HR mode is intended for use in dermatology	Same

	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 L-VI), including tanned skin.(HR. SHR Modes) The indications for use for the SILKPRO-S20S-810B 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 airs 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)	procedures requiring coagulation indications for use for the Soprano Trio diode laser HR module include : Benign vascular and vascular dependent lesions. 810nm Applicator Soprano Titanium 810 nm applicator intended use and indications for use： 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. 755nm Applicator Soprano Titanium 755 nm applicator intended use and indications for use： 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 Use on all skin types (Fitzpatrick I-VI) , including tanned skin . HR , and SHR Modes. NIR Applicator: NIR Applicator intended use and indications for use： 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.	
Operating theory	The working principle of SILKPRO Titanium Diode Laser System is selective photothermal effect. It uses its unique long pulse width laser to penetrate the epidermis to the hair follicle. The energy of the laser is preferentially absorbed by the melanin in the hair, so that the hair follicle produces high heat. Thereby destroying the structure of the hair follicle, making the hair lose the ability to regenerate, and achieving the purpose of hair removal. The treatment head adopts a uniquely designed sapphire dynamic cooling device.	The Soprano trio Diode Laser Module is a surgical device, which is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI); The working principle of Soprano trio Diode Laser Module is selective photothermal effect. It uses its unique long pulse width laser to penetrate the epidermis to the hair follicle. The energy of the laser is preferentially absorbed by the melanin in the hair, so that the hair follicle produces high heat. Thereby destroying the structure of the hair follicle, making the hair lose the ability to regenerate, and achieving the purpose of hair removal. The treatment head adopts a uniquely designed sapphire dynamic cooling device.	Same
Laser Type	GaA1As Diode Laser array	GaA1As Diode Laser array	Same
Handpiece tipmaterial	Sapphire	Sapphire	Same
Wavelength	SILKPRO-S20S-TWC: 755nm/810nm/1064nm Three in one combination wavelength	755nm/810nm/1064nm Three in one combination wavelength	Same
	SILKPRO-S20S-755A:755 nm	755 nm	Same

	SILKPRO-S20S-810B:810 nm	810 nm	Same
Spot size	SILKPRO-S20S-TWC: 10×40 mm^2	Soprano Trio: 4cm^2	Same
	SILKPRO-S20S-755A: 12×12 mm^2	755nm Applicator: 1.5 cm^2	Similar The spot size of the proposed device is similar to the predicate device, so this definition does not affect the safety and effectiveness.
	SILKPRO-S20S-810B: 10×20mm^2	810nm Applicator :2cm^2	Same
Pulse Width (ms)	SILKPRO-S20S-TWC: Up to 200 ms	Soprano Trio: Up to 200 ms	Same
	SILKPRO-S20S-755A : 3.3-200 ms	755nm Applicator: 3.3-200 ms	Same
	SILKPRO-S20S-810B : 3.3-200 ms	810nm Applicator : 3.3-200 ms	Same
Pulse Repetition Rate	SILKPRO-S20S-TWC: SHR：Up to 10 Hz	Soprano Trio: HR: Up to10 Hz SHR: Up to10 Hz	Same
	SILKPRO-S20S-755A:	755nm Applicator:	Same

	HR：0.5-3Hz SHR：5-10Hz	HR: 0.5-3 Hz SHR: 5-10 Hz	
	SILKPRO-S20S-810B: HR：0.5-3Hz SHR：5-10Hz	810nm Applicator: HR: 0.5-3 Hz SHR: 5-10 Hz	Same
Energy Density (Fluence)	SILKPRO-S20S-TWC SHR：2-8 J/cm^2	Soprano Trio: HR:2- 120 J/ cm^2 SHR: 2-20 J/ cm^2	Same
	SILKPRO-S20S-755A HR：Up to 120J/ cm^2 SHR：Up to 20J/ cm^2	755nm Applicator: HR: Up to 120J/ cm^2 SHR: Up to 20J/ cm^2	Same
	SILKPRO-S20S-810B HR：2-120J/ cm^2 SHR：2-20J/ cm^2	810nm Applicator: HR:2-120J/ cm^2 SHR:2-20J/ cm^2	Same
User Interface	LCD Color Touchscreen	LCD Color Touchscreen	Same
Laser classification	Class IV	Class IV	Same
Cooling system	TEC	TEC	Same
Software	Yes	Yes	Same
Delivery Devices (How supplied)	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	Same
Discussion for Substantially Equivalent (SE)	The proposed device SILKPRO Titanium Diode Laser System series products has the same purpose as the predicate device: product code, Regulation No., Regulatory Class , Controls, indications for use, Operating theory , Laser Type, Handpiece tipmaterial , wavelength, Spot size, Pulse Width (ms), Pulse Repetition Rate, Energy Density (Fluence) ,user interface, Laser classification, Cooling system , Software, delivery devices and Electromagnetic compatibility and electrical safefy compliance. 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 ANSI AAMI ES60601-1, IEC 60601-1-2, IEC 60601-2-22 and IEC 60825-1. Results confirmed the device meets the standards. All patient contacting materials were assessed as per ISO 10993-1 and found to be biocompatible.

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

Lotuxs believes that SILKPRO Titanium Diode Laser System series products is substantially equivalent to its predicate devices with same indications for use, similar technological characteristics. The non-clinical data for SILKPRO Titanium Diode Laser System series products supports the safety of the device and the biocompatibility, hardware and software verification and validation demonstrate that the SILKPRO Titanium Diode Laser System series products should perform as intended in the specified use conditions.

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