May 26, 2023

Smedtrum Medical Technology Co., Ltd.
Crimson Wu
Senior Regulatory Engineer
1F., No. 8, Ln. 97, Wugong Rd.,
New Taipei City, Xinzhuang Dist. 248016
Taiwan

Re: K230580
Trade/Device Name: Diode 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 28, 2023
Received: May 1, 2023

Dear Crimson 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)*
K230580

Device Name
Diode Laser System

Indications for Use *(Describe)*
The Diode Laser System includes 2 types of handpieces with same 1.2 x 1.4 cm spot size:

Single-Wavelength Handpiece
810nm wavelength
The 810nm wavelength handpiece is 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 FHR Modes)

Trio-Wavelength Handpiece
The Trio-Wavelength Handpiece combines 3 wavelengths (755+810+1064 nm) into a single handpiece. It is intended for temporary hair reduction in Fast Hair Removal Mode (FHR).

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
Diode Laser System

I. SUBMITTER

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Date of preparation: May 9th, 2023

II. DEVICE

Trade Name:	Diode Laser System
Common or Usual Name:	Surgical Laser Device
Product code:	GEX
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology. 21 C.F.R. § 878.4810, Device Class II

III. PREDICATE DEVICE

Manufacturer	Alma Lasers Inc.
Trade Name:	The Alma Soprano Titanium
Common or Usual Name:	Surgical Laser Device
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology. 21 C.F.R. § 878.4810, Device Class II
Premarket Notification:	K222064　Oct 12th, 2022

IV. DEVICE DESCRIPTION

Diode Laser System is a photothermal effect surgical laser device intended for prescription use and is comprised mainly of three components: console, handpieces and water-loop cooling system. There is plenty of melanin in hair follicles and hair shafts. Melanin scatters among hair bulbs and shaft structures (like medullary substance, cortex, and cuticula pili). The laser wavelengths that ST-803 Diode Laser

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System uses can be well absorbed by melanin, which causes a rapid increase in temperature, destroying surrounding hair follicles, and finally removing hair. The control panel is in the form of an LCD touch screen in front of device and displays for operating and monitoring the laser. The system can automatically identify different handpieces. The product includes 2 types of handpieces that are in the same spot size and 2 combinations of wavelengths.

The diode is exited to emit a high-power therapeutic laser beam intended to reduce unwanted body hair (e.g., armpit, leg, arm, back, chest and bikini line). It is intended to be used by a trained professional to emit a laser of wavelength around 810 nm or 755+810+1064 nm, delivered by a dedicated handpiece, to destroy hair follicles by heat.

V. INDICATIONS FOR USE

The Diode Laser System includes 2 types of handpieces with same 1.2 x 1.4 cm spot size:

Single-Wavelength Handpiece

810 nm wavelength

The 810 nm wavelength handpiece is 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 FHR Modes)

Trio-Wavelength Handpiece

The Trio-Wavelength Handpiece combines 3 wavelengths (755+810+1064 nm) into a single handpiece. It is intended for temporary hair reduction in Fast Hair Removal Mode (FHR).

VI. COMPARISON OF TECHNOLOGICAL CHARATERISTICS WITH THE PREDICATE DEVICE

Feature	**Proposed device**	**Predicate device (K222064)**
Device Name	Diode Laser System	The Alma Soprano Titanium
Product Code	GEX	GEX

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Feature	**Proposed device**	**Predicate device (K222064)**
Regulation No.	21 CFR 878.4810	21 CFR 878.4810
Device Class	Class II	Class II

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Indication for Use	The Diode Laser System includes 2 types of handpieces with same 1.2 x 1.4 cm spot size: Single-Wavelength Handpiece 810nm wavelength The 810nm wavelength handpiece is 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 FHR Modes) Trio-Wavelength Handpiece The Trio-Wavelength Handpiece combines 3 wavelengths (755+810+1064 nm) into a single handpiece. It is intended for temporary hair reduction in Fast Hair Removal Mode (FHR).	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 Titanium diode laser module HR mode 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. 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

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		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, 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.

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Feature	**Proposed device**			**Predicate device (K222064)**		
				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	GaA1As Diode Laser array			GaA1As Diode Laser array		
Laser Classification	Class IV			Class IV		
Laser Wavelength	810 nm and Trio-wavelength 755+810+1064 nm			810 nm, 755 nm, NIR and Trio-wavelength 755+810+1064 nm		
Laser Delivery System	Handpiece			Handpiece		
Beam Delivery Handpiece	810 nm and Trio-wavelength 755+810+1064 nm			810 nm and Trio-wavelength 755+810+1064 nm		
Laser firing Controls	LCD color Touchscreen			LCD color Touchscreen Footswitch		
Laser Module Power	1600W			600W/800W/1000W/1200W/ 1600W		
Fluence	Single-Wavelength	HR	FHR		HR	SHR
		1~50	1~20	810 nm	2~120	2~20

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Feature	**Proposed device**			**Predicate device (K222064)**		
		J/cm^2	J/cm^2	2 cm^2	J/cm^2	J/cm^2
				755 nm	Up to 120 J/cm^2	Up to 20 J/cm^2
				Trio-wavelength 4 cm^2	2~120 J/cm^2	2~20 J/cm^2
	Trio-Wavelength		1~8 J/cm^2	NIR	Min:10W Max:>25J	
Frequency	1, 2, 3, 5, 8,10 Hz (6 adjustable levels)			810 nm 2 cm^2	0.5~3 Hz	5~10 Hz
				755 nm	0.5~3 Hz	5~10 Hz
				Trio-wavelength 4 cm^2	Up to 10 Hz	Up to 10 Hz
				NIR	CW	
Pulse width (Max)	5~200 ms			810 nm: 3.3~200 ms 755 nm: 3.3~200 ms Trio-wavelength: Up to 200 ms		
Spot Size	Both handpieces: 1.2 cm×1.4 cm			810nm: 1 cm^2 and 2 cm^2, 755nm: 1.5 cm^2, Trio-wavelength: 2 cm^2 and 4 cm^2 NIR: 18 cm^2 and 6.4 cm^2		
Power Input	110-240VAC, 22-10A, 50/60 Hz			230 VAC, 16A, 50/60 Hz		
Cooling	water + air + TEC			water + air + TEC		
Appearance	119.5 cm x 58 cm x 61 cm, 55 Kg			120 cm x 39 cm x 38 cm, 84 Kg		

VII. PERFORMANCE DATA

The Diode Laser System has been determined through engineering testing to verify laser energy output and electrical safety.

Electrical safety and electromagnetic compatibility

The test results demonstrated that the proposed device complies with the following standards:

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

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IEC 60601-1-2:2020 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 60601-2-22:2019 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern since a failure of the software could result in minor injury to a patient or to a user of the device.

Sterilization and Shelf-Life

The proposed device is not provided sterile and does not need to be sterilized. The handpiece and the body are cleaned with a soft cloth moistened with ethanol of 70% strength or higher. The proposed device is reusable and does not have a restricted shelf-life.

Biocompatibility

The handpiece sapphire tip may be contact with the intact skin of patients. According to FDA guidance document "Use of International Standard ISO 10993-1, " Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process "" three biological effects were determined in following three test: Cytotoxicity, Sensitization and Irritation.

In Cytotoxicity test, L-929 cell cultured in 96-well plates were treated with extract of test article (100%, 75%, 50%, and 5% in MEM medium) and then incubated at 37℃ in cell incubator of 5% Diode for 24h. Viability % of the 100% extract of stainless steel and aluminum alloy is 83.2% and 87.9%, respectively, so the extract of test article passed test requirement and did not show potential cytotoxicity to mouse fibroblast L-929 cells.

In Skin sensitization test, Guinea Pig Maximization Test (GPMT) were performed for determination of the skin sensitizing potential of test article extraction. Under

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GPMT method, the results shows the test article did not cause delayed dermal contact sensitization in the guinea pig.

In Skin irritation test, the extraction solution of the test article (extraction in 0.9% sodium chloride injection and sesame oil) and control solution were treated on the backs of fur clipped rabbits. The appearance of each application site was recorded and scored after 1 hour, 24 hours and 72 hours treatment. The score of skin reaction of test extraction at different time point were 0 as negative control group and showed no potential skin irritation risk.

Three biological effects, cytotoxicity, sensitization and irritation testing, were performed and test results did not identify any biological response or risk. The Diode Laser System meets the ISO 10993-1 standard requirements for biocompatibility and no further characterization testing is required.

Bench testing

Bench testing was conducted to validate that the energy output parameters of the subject device are similar to those of the predicate device.

VIII. CONCLUSION

The Diode Laser System has the same intended use, similar indications for use, the same technological characteristics, the same energy used, and the same operating principles as its predicates. The non-clinical data and performance testing reports in this submission demonstrate that Diode Laser System meets the expected performance requirements. Any difference between the subject and predicate device do not raise new issues of safety or effectiveness. Based on above analysis, the Diode Laser System is as safe, as effective, and performs as well as the cited predicate device.