September 15, 2022

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: K221597
Trade/Device Name: CO2 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: August 3, 2022
Received: August 3, 2022

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
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)*
K221597

Device Name
CO2 Laser System

Indications for Use *(Describe)*
The CO2 Laser System is used for body soft tissue ablation, vaporization, excision and coagulation in dermatology, plastic surgery and general surgery.

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
CO_2 Laser System (K221597)

I. SUBMITTER

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Date of preparation: May 31th, 2022

II. DEVICE

Trade Name:	CO_2 Laser System
Common or Usual Name:	Surgical Laser Device
Classification Name:	GEX–Powered Laser Surgical Instrument 21 C.F.R. § 878.4810, Device Class II

III. PREDICATE DEVICE

Trade Name:	CO_2 Laser Therapy System
Common or Usual Name:	Surgical Laser Device
Classification Name:	GEX–Powered Laser Surgical Instrument 21 C.F.R. § 878.4810, Device Class II
Premarket Notification:	K201109　Sep 15th, 2020

IV. DEVICE DESCRIPTION

CO_2 Laser System is a carbon dioxide surgical laser device intended for prescription use and is comprised mainly of three components: console, articulated arm and footswitch.CO_2 Laser System contains a radio-frequency excited CO_2 laser tube which generates laser sources at nominal wavelength of 10,600 nm. As CO_2 laser radiation is invisible; therefore, a low-power, visible aiming laser source (650 nm) is required to position the treatment laser beam. The output of laser beam is delivered through articulated arm to a fractional handpiece or normal handpiece. 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 physician activates laser emission by means of a footswitch. The fractional handpiece is suited mainly for general surgical application.

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When the laser contacts human tissue, the laser energy is absorbed by water in the target tissue, resulting in a very rapid, highly localized temperature increase to the tissue. The instantaneous temperature-increase heats up the water and causes evaporation of the affected tissue. Some heat is absorbed by tissue adjacent to the treatment area, causing tissue coagulation which induces hemostasis as well as thermal stimulation of deep skin layers, that inducing fibroblast stimulation and neocollagenesis.

The CO_2 Laser System is capable of producing continuous-wave, pulsed laser or fractional laser radiation. The physician can optimize the parameter for different applications by adjusting the energy of laser pulse and output pattern.

V. INDICATIONS FOR USE

The CO_2 Laser System is used for body soft tissue ablation, vaporization, excision and coagulation in dermatology, plastic surgery and general surgery.

VI. COMPARISON OF TECHNOLOGICAL CHARATERISTICS WITH THE PREDICATE DEVICE

Feature	**Proposed device**	**Predicate device (K201109)**
Device Name	CO_2 Laser System	CO2 Laser Therapy System
Product Code	GEX	GEX
Regulation No.	21 CFR 878.4810	21 CFR 878.4810
Device Class	Class II	Class II
Indication for Use	The CO2 Laser System is used for body soft tissue ablation, vaporization, excision and coagulation in dermatology, plastic surgery and general surgery.	The CO2 Laser Therapy System is used for body soft tissue vaporization and coagulation in dermatology and plastic surgery, general surgery, gynecology.
Laser Type	RF Sealed-off CO_2	RF Sealed-off CO2
Laser Classification	Class 4	Class 4
CO_2 Laser Wavelength	10600 nm	10600 nm
Aiming Beam Wavelength	< 2 mw /650 nm /Semiconductor Laser LD	< 2 mw /650 nm /Semiconductor Laser LD
Max. Aiming Beam Power Watts	2 mW	2 mW
Laser Delivery System	Articulated arm with counterweight	Articulated arm with counterweight
Beam Delivery Handpiece	2 Normal Handpieces or 1 Fractional Handpiece	2 Normal Handpieces or 1 Fractional Handpiece
Laser firing Controls	LCD color Touchscreen Footswitch	LCD color Touchscreen Footswitch

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Feature	**Proposed device**		**Predicate device (K201109)**	
Max. Output Power Watts	35 W		HS-411: 35 W HS-411A: 55 W	
Scan Area Size	2x2 mm~20x20 mm		2x2 mm~20x20 mm	
Pulse Duration	CW	NA	CW	NA
	Single	1~375 ms	Single	10~500ms
	Pulse	Pulse width: 5~375 ms Delay time: 1~500 ms	Pulse	On time: 5~500 ms Off time: 1-500 ms
	S-Pulse	Pulse width: 1~4 ms Delay time: 1~100 ms	S. Pulse	On time: 1~4 ms Off time: 1-100 ms
	U-pulse	Pulse width: 0.1-0.9 ms Delay time: 1-100 ms	U pulse	On time: 0.1-0.9 ms Off time: 1-100 ms
Fractional Pulse Energy	1-300 mJ/dot		1-300 mJ/dot	
Spot Size	120 µm （fractional）		150 µm （fractional）	
Spot Density (DPA)/ cm^2	25, 36, 49, 64, 81, 100, 121, 144, 169, 196, 225, 256, 289, 324, 361, 400, 441, 484, 529, 784, 1024, 1521, 2025, 2500, 3025 dots.		25, 36, 49, 64, 81, 100, 121, 144, 169, 196, 225, 256, 289, 324, 361, 400, 441, 484, 529, 784, 1024, 1521, 2025, 2500, 3025 dots.	
Operational Mode	Fractional mode, and normal mode (CW, Single, Pulse, S. pulse, U. pulse)		Fractional mode, and normal mode (CW, Single, Pulse, S. pulse, U. pulse)	
Cooling System	Forced-air cooling		Forced-air cooling	
Power Input	100-240VAC, 50/60 Hz		100-240VAC, 50/60 Hz	
Dimension	188 cm x 61 cm x 53.4 cm (H x W x D)		113 cm x 45 cm x 50 cm (H x W x D)	
Weight	50 Kg		55 Kg	
Software	Yes. Verification and validation testing of the software are performed.		Yes	

VII. PERFORMANCE DATA

The CO_2 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:

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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 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and requirements

IEC 60601-2-22:2007(third edition)+A1:2012 for use in conjunction with IEC 60601-1:2005 (third edition)+A1:2012 Medical electrical equipment - Part 2-22: Particular requirements for the 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 isopropyl alcohol or ethanol of 70% strength or higher. The proposed device is reusable and does not have a restricted shelf-life.

VIII. CONCLUSION

The CO_2 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 CO_2 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 CO_2 Laser System is substantial equivalent to the cited predicate device.