December 20, 2024

Beijing ADSS Development Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401
China

Re: K241670
Trade/Device Name: Fractional CO2 Laser Therapy System (FG900-S); Fractional CO2 Laser Therapy System (FG900-S2)
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 15, 2024
Received: November 15, 2024

Dear Ray Wang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2024.12.20 12:41:15 -05'00'

for Tanisha Hithe
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.

Submission Number *(if known)*

K241670

Device Name

Fractional CO2 Laser Therapy System (FG900-S);
Fractional CO2 Laser Therapy System (FG900-S2)

Indications for Use *(Describe)*

Fractional CO2 Laser Therapy 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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The assigned 510(k) Number: K241670

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 2024.06.04
2. Sponsor Identification

Beijing ADSS Development Co., Ltd.

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Fractional CO2 Laser Therapy System

Common Name: Powered Laser Surgical Instrument, Powered Laser Surgical Instrument With Microbeam\Fractional Output

Regulatory Information
Classification Name: Powered Laser Surgical Instrument, Powered Laser Surgical Instrument With Microbeam\Fractional Output
Classification: II
Product Code: GEX
Regulation Number: 878.4810
Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

510(k) Number: K221597
Product Name: Co2 Laser System
Manufacturer: Smedtrum Medical Technology Co., Ltd.

6. Device Description

Fractional CO2 Laser Therapy System consists of a main unit, a light guide arm (including a treatment head), a foot switch, and protective goggles. The fractional CO2 laser penetrates directly into the dermis utilizing the thermal effect of laser, instantly vaporizes the tissue in the lesion area. Parameters such as the laser energy density required for the treatment are set by the user appropriately. The Fractional CO2 Laser Machine has two operational modes, fractional mode and normal mode.

7. Indication For Use Statement:

Fractional CO2 Laser Therapy System is used for body soft tissue ablation, vaporization, excision and coagulation in dermatology,plastic surgery and general surgery.

8. Substantially Equivalent (SE) Comparison

Tab 1 General Comparison

Item	**Proposed Device**	**Predicate Device (K221597)**	**Remark**
Manufacturer	Beijing ADSS Development Co.,Ltd.	Smedtrum Medical Technology Co., Ltd.	/
Device Name	Fractional CO2 Laser Therapy System	CO2 Laser System	/
Intended use	Fractional CO2 Laser Therapy System is used for body soft tissue ablation, vaporization, excision and coagulation in dermatology,plastic surgery and general surgery.	The CO2 Laser System is used for body soft tissue ablation, vaporization,excision and coagulation in dermatology, plastic surgery and general surgery.	Same
Laser Wavelength	10.6μm	10.6μm	Same
Laser medium/energy source	CO2	CO2	Same
Max. Output Power Watts	Max 35W	Max 35W	Same
Operational Mode	Fractional mode, and normal mode (Continuous output , Single pluse, Repetitive pulse)	Fractional mode, and normal mode (CW, Single, Pulse, S-pulse,U- pulse)	Analysis1
Aiming beam	Red diode laser,Max 5mW	< 2 mw /650 nm /Semiconductor Laser LD	Analysis2
Cooling	Air cooling	Forced-air cooling	Same
Beam Delivery Handpiece	Articulated arm with counterweight	Articulated arm with counterweight	Same
Laser firing Controls	LCD color Touchscreen Footswitch	LCD color Touchscreen Footswitch	Same
Electrical Requirements	230V,50/60HZ	110-240VAC,50-60Hz	Analysis3
Fractional Model			
Pulse Energy	1-300mj/dot	1-300mj/dot	Same
Spot size	0.12mm	0.12mm	Same
Spot Density (DPA)/ cm2	25, 36, 49, 64, 81, 100, 121, 144, 169, 196, 225, 256, 289, 324, 361, 400,	25, 36, 49, 64, 81, 100, 121, 144, 169, 196, 225, 256, 289, 324,	Same

	441, 484, 529, 784, 1024, 1521, 2025, 2500, 3025 dots.		361, 400, 441, 484, 529, 784, 1024, 1521, 2025, 2500, 3025 dots.		
Scan Area Size	2x2mm-20x20mm		2x2mm-20x20mm		Same
Normal Model					
Pulse Duration	Continuous output	N/A	CW	N/A	Same
	Single pulse	1~375 ms	single	1~375 ms	Same
	Repetitive pulse	Pulse width: 0.1~375 ms Delay time: 1-500ms	pluse	Pulse width: 5~375 ms Delay time: 1~500 ms	Same
			S-Pulse	Pulse width: 1~4 ms Delay time: 1~100 ms	
			U-pulse	Pulse width: 0.1-0.9 ms Delay time: 1-100 ms	

Analysis

1. Although the operating modes of proposed device and predicate device are different, the parameters in different operating modes are comparable.Therefore, this difference will not affect safety and effectiveness of the proposed device.

2.The aiming beam power of proposed device does not cause heat or energy hazard to the patients during the treatment procedure. Therefore, this difference will not affect safety and effectiveness of the proposed device.

3.The electrical requirements for the proposed device is different from the predicate device. However, electrical safety and EMC test has been conducted on the proposed device and the test result show that the device can work normally under this electrical requirements. Therefore, this difference will not affect safety and effectiveness of the proposed device.

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements
- IEC 60601-2-22: 2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- ISO 10993-10 Fourth edition 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- IEC 60601-1-2 Edition 4.1 2020-09, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Test

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

Based on the nonclinical tests performed , the subject device is as safe, as effective, and performance as well as the legally marketed predicate device, CO2 Laser System cleared under K221597.