October 26, 2026

Sanhe PERFECTLASER Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Bldg. #15, Xiyuehui, #5, Yihe N. Rd.
Fangshan District
Beijing, 102401
China

Re: K262627
Trade/Device Name: Fractional CO2 Laser Therapy System (Z121)
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: July 29, 2026
Received: July 29, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2026.10.26 22:47:19 -04'00'

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.

510(k) Number *(if known)*
K262627

Device Name
Fractional CO2 Laser Therapy System (Z121)

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. Fractional functionality is intended for skin resurfacing only.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K262627

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

1. Date of Preparation: 10/01/2026
2. Sponsor Identification

Sanhe PERFECTLASER Technology Co., Ltd.
Room 1003, Building A1 (A-1), Enterprise Headquarters, Yanjiao Modern Service Industry Park Pilot Zone, South Side of Nancheng Street, East Side of Shuichang South Road, Yanjiao High-tech Zone, Sanhe City, Langfang City, Hebei Province, China

Contact Person: Yongchao Lian
Position: Certification Engineer
Tel: +86-15201170689
Email: 876010234@qq.com

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, 102401, China

Tel: +86-18910677558
Fax: +86-10-56335780
Email: information@believe-med.com

4. Identification of Proposed Device

Trade Name: Fractional CO2 Laser Therapy System

Common Name: Powered Laser Surgical Instrument (Z121)

Regulatory Information

Classification Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology

Classification: II

Product Code: GEX

Regulation Number: 878.4810

Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

510(k) Number: K241670

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

Manufacturer: Beijing ADSS Development Co., Ltd.

Reference Device 1: K162169

Product Name: EdgeOne CO2 Laser

Manufacturer: Jeisys Medical Inc.

6. Device Description

Fractional CO2 laser therapy system uses the thermal effect of laser to directly reach the dermis, instantly vaporize the tissue in the affected area, and stimulate collagen proliferation, thereby promoting a series of skin reactions such as tissue repair and collagen reconstruction.The parameters such as laser energy density required for treatment are set by the user.

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. Fractional functionality is intended for skin resurfacing only.

8. Substantially Equivalent (SE) Comparison

Tab 1 General Comparison

Item	**Proposed Device**	**Predicated Device K241670**	**Reference Device 1 K162169**	**Remark**
Manufacturer	Sanhe PERFECTLASER Technology Co., Ltd.	Beijing ADSS Development Co.,Ltd.	Jeisys Medical Inc.	/
Device Name	Fractional CO2 laser therapy system	Fractional CO2 Laser Therapy System	EdgeOne CO2 Laser	/
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.Fractional functionality is intended for skin resurfacing only.	Fractional CO2 Laser Therapy System is used for body soft tissue ablation, vaporization, excision and coagulation in dermatology,plastic surgery and general surgery.	It is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology(ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.	Same
Laser Wavelength	10.6μm	10.6μm	10.6μm	Same
Max. Output Power Watts	Max 35W	Max 35W	30W	Same as K241670
Operational Mode	Fractional mode, and normal mode (Continuous output , Single pluse, Repetitive pulse)	Fractional mode, and normal mode (Continuous output , Single pluse, Repetitive pulse)	Fractional mode, normal mode (CW, Pulse, Single Pulse, Repeat, Group pulse, Ultra)	Same
Aiming beam	Red diode laser,Max	Red diode laser,Max	Diode laser(Red) 655	Analysis1

	3mW		5mW		+/-10nm, Max 1mW	
Cooling	Air cooling		Air cooling		Water	Same as K241670
Beam Delivery Handpiece	Articulated arm with counterweight		Articulated arm with counterweight		Articulated arm	Same
Laser firing Controls	LCD color Touchscreen Footswitch		LCD color Touchscreen Footswitch		LCD touch screen	Same
Electrical Requirements	100V-230V,50/60Hz		230V,50/60HZ		230V~, 50/60Hz, 500VA(max. laser output),100VA(standby)	Analysis2
Pulse Energy	1-300mj/point		1-300mj/dot		1-300mJ	Same
Spot size	0.12 mm		0.12mm		120um, 350um, 800um	Same as K241670
Spot Density (DPA)/ cm2	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.		Spot density 0-42.4%	Same as K241670
Scan Area Size	2x2 mm-20x20 mm		2x2mm-20x20mm		15 x 15mm2	Same as K241670
Pulse Duration (normal mode)	Continuous output	N/A	Continuous output	N/A	1-1000ms	Analysis3
	Single pulse	1-10 ms	Single pulse	1~375 ms		
	Repetitive pulse	Pulse width: 1-1000ms Delay time: 1-1000ms	Repetitive pulse	Pulse width: 0.1~375 ms Delay time: 1-500ms		

NOTE：

For fractional skin-resurfacing functionality, the recommended parameter combination is:

Pulse energy : < 70 mJ/dot;

Uniform spot density : < 500 dots/cm2 leading to skin coverage of ~5% or less;

Spot size ： 0.12 mm.

Analysis

Analysis 1: 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.

Analysis 2: 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.

Analysis 3: In Single Pulse mode, the pulse width of the Proposed Device (1–10 ms) falls within the pulse width range of the Predicate Device (1–375 ms), ensuring no higher risk of thermal injury. For the pulse width difference in Repetitive Pulse mode, we have introduced Reference Device K162169. Under the same intended use, the pulse width range of the Reference Device (1–1000 ms) fully covers that of the Proposed Device, guaranteeing equivalent safety and effectiveness. Therefore, this difference will not affect the 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 non-clinical tests performed, the subject device is as safe, as effective, and

performance as well as the legally marketed predicate device, Fractional CO2 Laser Therapy System cleared under K241670.