December 19, 2025

Sanhe LEFIS Electronics Co., Ltd.
Dandan Wang
Registered Manager
Building 11 #1-101, Phase 1, Zhongnan High tech· Yanjiao Sci
ence and Technology Innovation Smart Valley Industrial Park
Langfang, Hebei 065201
China

Re: K250998
Trade/Device Name: CO2 Laser Therapy System (Model: LFS-D9U)
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: March 26, 2025
Received: April 1, 2025

Dear Dandan 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.12.19 22:59:09 -05'00'

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)*
K250998

Device Name
CO2 Laser Therapy System (Model: LFS-D9U)

Indications for Use *(Describe)*
The equipment is used for human tissue vaporization, coagulation in dermatology, plastic surgery, and general surgery. The Classical scanner is only for the treatment of wrinkles and skin resurfacing.

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: K250998

510(k) Summary

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 Submission: 2025/12/17

2. Sponsor Identification

Sanhe LEFIS Electronics Co., Ltd.

Building 11 #1-101, Phase 1, Zhongnan High tech· Yanjiao Science and Technology Innovation Smart Valley Industrial Park 1, South Side of Liushan Street and West Side of Gushan West Road, Yanjiao High tech Zone, Sanhe City, 065201 Langfang City, Hebei Province, China

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3. Designated Submission Correspondent

Ms. Dandan Wang

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Fax: +86-316-3096027

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4. Identification of Proposed Device

Trade Name: CO2 Laser Therapy System (Model: LFS-D9U)

Common Name: Surgical Laser Device

Regulatory Information

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

Classification: II

Product Code: GEX

Regulation Number: 21CFR 878.4810

Review Panel: General & Plastic Surgery

5. Indication For Use Statement:

The equipment is used for human tissue vaporization, coagulation in dermatology, plastic surgery, and general surgery. The classical scanner is only for the treatment of wrinkles and skin resurfacing.

6. Environment of Use

healthcare facility/hospital

7. Device Description

CO2 Laser Therapy System (Model: LFS-D9U) uses infrared beam with a wavelength of 10.6 μ m for human tissue vaporization, coagulation in dermatology, plastic surgery, and general surgery. The classical scanner is only for the treatment of wrinkles and skin resurfacing. The device comprises a main unit, therapy head, light guide system, and footswitch.

8. Materials

Components	Material	Category	Contact Level	Contact Duration
Treatment Head	Al Alloy	Surface device	Intact skin	Short-term (<24h)

The treatment hand piece used in the system has passed the Biocompatibility test. For details, please refer to "Biocompatibility Discussion".

9. Identification of Predicate Device(s)

510(k) Number: K191518
Product Name: CO2 Laser System (Model: GP900F)
Manufacturer: SHENZHEN GSD TECH CO., LTD

Reference Device 1: K201109
Product Name: CO2 Laser Therapy System
Manufacturer: Shanghai Apolo Medical Technology Co., Ltd.

Reference Device 2: K162169
Product Name: EdgeOne CO2 Laser
Manufacturer: Jeisys Medical Inc.

10. 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:

- ANSI/AAMI ES60601-1:2005, ES60601-1:2005/AMD1:2012, ES60601-1:2005/AMD2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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 disturbances - Requirements and tests

- 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
- IEC 60825-1 2014 Safety of laser products - Part 1: Equipment classification, and requirements

The body-contacting components of this device are the treatment head. The biocompatibility evaluation for the CO2 Laser Systems was conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process'". The treatment head is considered skin and subcutaneous tissue contacting for a duration of less than 24 hours. The biocompatible testing included In Vitro Cytotoxicity, Skin Sensitization and Intracutaneous Reactivity was conducted in compliance with:

- ISO 10993-5: 2009 Biological Evaluation of Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993- 10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation.

We have also conducted:

- Software verification and validation test according to the requirements of the FDA Guidance "Content of Premarket Submissions for Device Software Functions". The software for this device requires basic documentation level. Software validation demonstrated that the software functions as specified in the software requirement specifications.
- Bench performance testing to show that the device delivers set laser energy parameters within specifications.

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 75% strength or higher. The proposed device is reusable and does not have a restricted shelf-life.

11. Technological characteristics and substantial equivalence:

Table 1 General Comparison

ITEM	Proposed Device K250998	Predicate Device K191518	Reference Device 1 K201109	Reference Device 2 K162169	Remark
Device Name	CO2 Laser Therapy System	CO2 Laser System (Model: GP900F)	CO2 Laser Therapy System	EdgeOne CO2 Laser	/
Manufacturer	Sanhe LEFIS Electronics Co., Ltd.	SHENZHEN GSD TECH CO., LTD	Shanghai Apolo Medical Technology Co., Ltd.	Jeisys Medical Inc.	/
Product Code	GEX	GEX	GEX	GEX, ONG	Same
Class	Class II	Class II	Class II	Class II	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Intended Use	The equipment is used for human tissue vaporization, coagulation in dermatology, plastic surgery, and general surgery. The Classical scanner is only for the treatment of wrinkles and skin resurfacing.	The equipment is used for human tissue vaporization, coagulation in dermatology, plastic surgery, and general surgery. The Classical scanner is only for the treatment of wrinkles and skin resurfacing.	The CO2 Laser Therapy System is used for body soft tissue vaporization and coagulation in dermatology and plastic surgery, general surgery, gynecology.	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	Same

				for ablative skin resurfacing.	
Indication for use	Prescription Use	Prescription Use	Prescription Use	Prescription Use	Same

Table 2 Performance Comparison

ITEM	**Proposed Device K250998**	**Predicate Device K191518**	**Reference Device 1 K201109**	**Reference Device 2 K162169**	**Remark**
Laser Medium	CO2	CO2	CO2	CO2	Same
Wavelength	10600nm	10600nm	10600nm	10600nm	Same
Output Power (Maximum)	30W	30W	HS-411: 1~35W HS-411A: 1~55W	30W	Same
Work Mode	Classical mode, and Surgical Mode (Continuous, Repetitive Pulses)	Classical mode, Surgical mode (Single Pulse, Continuous, Muti-Pulse)	Fractional mode, normal mode and vaginal (CW, Single, Pulse, S.pulse, U.pulse)	Fractional mode, normal mode (CW, Pulse, Single Pulse, Repeat, Group pulse, Ultra)	Analysis 1
Classical Pulse Energy	1mJ~300mJ	0.1mJ~300mJ	1mJ~300mJ	1mJ~300mJ	Same

Spot Size	0.5mm	0.5mm	150um (fractional)	120um, 350um, 800um	Same as K191518
Scan Area Size	2.0X2.0mm-20X20mm	/	2.0X2.0mm-20X20mm	15mmX15mm	Same as K201109
Spot density	DPA/ cm^2: 16, 25, 36, 49, 64, 81, 100, 121, 144, 169, 196, 225, 256, 289, 324, 361, 400 dots.	/	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.	Spot density 0-42.4%	Within range of K201109
Pulse Width	Classical mode: 1-10ms； Normal Mode: 1 ms~500 ms	Classical mode: 0.1ms~10ms Surgical mode: 0.5ms~1000ms	Single mode: 10~500 ms Pulse: On time:5~500 ms Pulse:Off time: 1~500 ms S.Pulse: On time:1~4 ms S.Pulse:Off time: 1~100 ms U.Pulse: On time:0.1~0.9 ms U.Pulse:Off time: 1~100 ms	1-1000ms	Analysis 2
Repetition Rate	10-500Hz	10-500Hz	/	10-500Hz	Same
Aiming Beam	Semiconductor laser, 600nm-660nm	Red diode laser 650nm±10nm	Semiconductor Laser LD 650nm	Diode laser (Red) 655 +/- 10nm	Similar

Max.Aimig BeamPower	5mW	5mW	2mW	1mW	Similar
Laser Class	Class 4	Class 4	Class 4	Class 4	Same
Cooling method for treated skin	Air cooling	Air cooling	/	Water cooling	Similar
Control System	Touch screen, footswitch	Touch screen, footswitch	Touch screen, footswitch	Touch screen, footswitch	Same
Power Input	110VAC, 60Hz	110-240VAC, 50-60Hz	/	230V~, 50/60Hz,	Same
Weight	65Kg	46Kg	/	/	Similar
Dimensions	550*430*1200mm	480mm*380mm*1053mm	/	/	Similar

Table 3 Safety Comparison

ITEM	Proposed Device	Predicate Device K191518	Reference Device 1 K201109	Reference Device 2 K162169	Remark
Biocompatibility	Passed the test as per ISO 10993-5， ISO 10993-10, ISO10993-23	Passed the test as per ISO 10993-5 and ISO 10993-10	Passed the test as per ISO 10993-5 and ISO 10993-10	Passed the test as per ISO 10993-5 and ISO 10993-10	Same
Patient Contact Sites	Skin	Skin	Skin	Skin	Same
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Same

Analysis 1: Working Mode

The differences between working modes are merely in terms of descriptions. The parameter values and intended uses are consistent. The correspondence of the two modes is as follows.

ITEM	Proposed Device	Predicate Device1 K191518	Note
Work Mode	Surgical Mode（Continuous, **Repetitive Pulses**）	Surgical mode (Single Pulse, Continuous, **Muti-Pulse**)	We have two modes, Continuous and Repetitive Pulses, which are within the scope of the Predicate device. Repetitive Pulses and Multi - Pulse are just different in wording

Analysis 2: Pulse Width

Classical mode: Matches the Predicate Device (K191518: Classical mode, 0.1–10 ms) – the slight lower bound difference (0.1 ms vs. 1 ms) is clinically insignificant, as both ranges fall within the safe and effective window for skin resurfacing, avoiding excessive thermal damage or ineffective tissue ablation.

Normal mode: Aligns with the Predicate Device (K191518: Surgical mode, 0.5–1000 ms) – the Proposed Device's 1–500 ms range is a subset of the Predicate's range, ensuring no higher risk of thermal injury. Reference Device 2 (K162169: 1–1000 ms) has a wider range, but the Proposed Device's range is fully contained within it, guaranteeing equivalent safety and effectiveness. Reference Device 1 (K201109) lists multiple pulse width sub-modes (e.g., Single Pulse: 10–500 ms; U.Pulse: 0.1–0.9 ms), all of which overlap with the Proposed Device's ranges. So this difference will not affect safety and effectiveness of the proposed device.

Conclusion:

CO2 Laser System is substantial equivalent to the predicate device.

12. Clinical Test Conclusion

No clinical study is included in this submission.

13. Substantially Equivalent(SE) Conclusion

The CO2Laser Therapy 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 CO2Laser Therapy 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 CO2Laser System is substantial equivalent to the cited predicate device.