January 27, 2025

Beijing Sano Laser S&T Development Co., Ltd.
% Owen He
Consultant
Microkn Medical Technology Service(Shanghai) Co.,Ltd Company
Room 901, Huafa Center, 889 Pinglu Road, Jing 'an District
Shanghai, 200040
China

Re: K242941
Trade/Device Name: CO2 Laser Therapy Systems (SHE-LSP003-1)
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: December 31, 2024
Received: December 31, 2024

Dear Owen He:

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: 2025.01.27 11:34:46 -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)*

K242941

Device Name

CO2 Laser Therapy Systems (SHE-LSP003-1)

Indications for Use *(Describe)*

The CO2 Laser Therapy Systems 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.

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510(k) #: K242941

510(k) Summary

Prepared on: 2025-01-24

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Beijing Sano Laser S&T Development Co., Ltd
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Correspondent Contact Telephone	+86 17721293816
Correspondent Contact	Mr. Owen He
Correspondent Contact Email	fda@microkn.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CO2 Laser Therapy Systems (SHE-LSP003-1)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code(s)	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K161925	CO2 Laser Therapy Machine	GEX
K241670	Fractional CO2 Laser Therapy System	GEX

Device Description Summary

21 CFR 807.92(a)(4)

CO2 Laser Therapy Systems is monochromatic light with strong penetration and precise focusing; When a continuous laser beam with a certain energy irradiates biological tissue, the instantaneous high temperature causes photo induced solidification and photo induced vaporization to irradiated tissue. With modulation pulse mode of CO2 laser, treatment effect can be achieved by control of laser emission frequency. After choosing laser Power, despite the frequency of laser emission, the laser is continuously output at a fixed Interval Time of 1 ms. Changes in frequency doesn't affect interval time.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication for use is the same with predicate device K241670.

Technological Comparison

21 CFR 807.92(a)(6)

We chose KI61925 (CO2 Laser Therapy Machine) as the equivalent product in the normal mode. At the same time, K241670 (Fractional CO2 Laser Therapy System) is selected as the equivalent device in Fractional mode.
In Normal Mode. the subject device has the same technical characteristics as the predicate device K161925 in wavelength, laser type, laser classification, pulse width range and frequency. In Fractional mode, the subject device's parameters (density/spot range, pulse energy, and spot size) is within the range of predicate device K241670. There is minor difference in pulse width range (0.1~9.9ms vs. 0.1~2.6ms).
However, such differences will not affect the actual safety and effectiveness of this product, and we have also made a detailed and accurate analysis of this in the Substantial Equivalence Discussion in the document. Meanwhile, although there are slight differences in this product, However, all comply with the requirements of IEC 60601-1, IEC 60601-2-22, IEC 60601-1-2 and IEC/TR 60601-4-2.
The proposed device is as safe and effective as a legally marketed predicate device, and does not raise new safety or effectiveness issues, and the proposed device is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

All nonclinical testing performed on new devices is to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards. Results of the testing demonstrate the compliance to the standards and matching the performance of new devices to the predicate devices. The following performance data were provided in support of the substantial equivalence determination.

- IEC 60601-1: Edition 3.2 2020-08 Medical electrical device Part I: General requirements for basic safety and essential performance
- IEC 60601-1-2: Edition 4.1 2020-09 Medical electrical equipment- Part 1-2: General requiirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
- IEC 60601-2-22: Edition 3.1 2012-10 Medical electrical equipment - Part 2-22: Particular irequirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC/TR 60601-4-2:2016 Medical electrical equipment - Par4.2: Guidance a1nd interpretation - electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60825-1: Edition 2.0 2007-03 Safety of laser products -Part 1: Equipment classification and requirements
- ISO 10993-5: Third Edition 2009-06-01Biological evaluation of medical devices -- Part 5: Tests: for In Vitro cytotoxicity
- ISO 10993-10: Fourth Edition 2021-11 Biological evaluation of medical devices - Part 10: Tes:ts for irritation and delayed-type hypersensitivity
- ISO 10993-23: First Edition 2021-01 Biological evaluation of medical devices - Part 23: Tes:ts for irritation

No clinical study is included in this submission. The device met all the criteria mentioned above and passed the test results. Based on the nonclinical tests performed , the subject device is as safe, as effective, and performance as well as the legally marketed predicate devices, cleared under K241670 and K161925.