November 7, 2025

HEBEI KEYLASER SCI-TECH 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: K252519
Trade/Device Name: CO2 Laser Therapy System (K106)
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 11, 2025
Received: August 11, 2025

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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.11.07 21:53:10 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K252519

Device Name
CO2 Laser Therapy System (K106)

Indications for Use *(Describe)*
The CO2 Laser Therapy System is used for soft tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

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: K252519

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 Preparation: 11/06/2025
2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: CO2 Laser Therapy System (K106)

Common Name: Powered Laser Surgical Instrument

Regulatory Information
Classification Name: Powered Laser Surgical Instrument
Classification: II
Product Code: GEX
Regulation Number: 878.4810
Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

510(k) Number: K161925
Product Name: CO2 Laser Therapy Machine
Manufacturer: Beijing Adss Development Co., Ltd

6. Device Description

CO2 Laser Therapy System is a laser beam generated by electrically excited carbon dioxide gas molecules, which has a very small divergence angle and high energy density. After focusing, it can reach a power of several kilowatts per square centimeter. Has the functions of vaporization and coagulation. The unfocused original light beam irradiates the lesion tissue, which can cause coagulation of biological tissue. The CO2 laser penetrates the tissue deeper, and after irradiation, it can heat and treat the deep tissue.

7. Indications For Use Statement:

The CO2 Laser Therapy System is used for soft tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

8. Substantially Equivalent (SE) Comparison

Tab 1 General Comparison

Item	Proposed Device	Predicate Device (K161925)	Remark
Product Code	GEX	GEX	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Class	2	2	SE
Where used	hospital	hospital	SE
Intended Use	The CO2 Laser Therapy System is used for soft tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	The CO2 Laser Therapy Machine is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	SE

Tab 2 Performance Comparison

Item	Proposed Device			Predicate Device (K161925)			Remark
Maximum Power	30W			30W			SE
Work Mode	Surgery (Single Pulse, Continuous, Muti-Pulse)			Surgery (Single Pulse, Continuous, Muti-Pulse)			SE
Wavelength	10.6 um			10.6 um			SE
Beam Delivery	7 joint light guide arm			7 knucklearmkey joints light arm			SE
Aiming Beam	630-650nm red diode laser (≤5 mW)			650nm red diode laser (0.5 mW)			Similar
Spot Size	0.5 mm			0.5 mm			SE
Pulse Setting	Single Pulse		10-1000ms	Single Pulse		10-1000ms	Within Range
	MutiPulse	Pulse Time	10-1000ms	Muti-Pulse	Time On	10-1000ms	
		Interval Time	10-1000ms		Time Off	10-1000ms	
	continuous		1-30W	continuous		0-30W	
Control System	Touch screen, footswitch			Touch screen, footswitch			SE
Laser Operation	Footswitch			Footswitch			SE
Laser medium/energy source	CO2			CO2			SE
Cooling System	Air cooling			Air cooling			SE
Cleaning Method	70% isopropyl alcohol			70% medical alcohol			SE

Dimension	63*54* 116cm(without light arm)	FG 900	56*46*112 cm	Analysis
		FG 900-B	60*54*32cm	
		FG 900-C	46*42*125cm	
Weight	56Kg	FG 900	49 kg	Analysis
		FG 900-B	28kg	
		FG 900-C	43kg	
Power input	AC 110V/60Hz	AC 110V/50Hz-60Hz		Similar

Tab 3 Safety Comparison

Item	Proposed Device	Predicate Device K161925	Remark
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825-1	Comply with IEC 60601-2-22, IEC 60825-1	SE

Analysis

The only difference between proposed device and predicate device is appearance (dimension, weight), which does not affect the safety and effectiveness of proposed device. Based on the nonclinical tests performed, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate 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, CO2 Laser Therapy Machine cleared under K161925.