



April 24, 2025

Zhuozhou Summer Star Technologies 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: K250183

Trade/Device Name: CO2 Laser System (CO2 Laser SST-L23)
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: January 22, 2025
Received: January 22, 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: 2025.04.24
19:23:43 -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

Indications for Use

510(k) Number (if known)

K250183

Device Name

CO2 Laser System (CO2 Laser SST-L23)

Indications for Use (Describe)

CO2 Laser System is used for human 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.

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
PRASStaff@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."

The assigned 510(k) Number: K250183

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: 2025.01.22

2. Sponsor Identification

Zhuozhou Summer Star Technologies Co.,Ltd

No. 502, building 2, junheyungu industrial park, Zhuozhou, Baoding, Hebei province, China

Contact Person: Lei Yan

Position: General Manager

Tel: +86- 13693100103

Email: 946280852@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: CO2 Laser System

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: K200042

Product Name: CO2 Laser System

Manufacturer: Beijing Superlaser Technology Co., Ltd.

6. Device Description

CO2 Laser 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 for vaporization. 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. Indication For Use Statement:

CO2 Laser System is used for human 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 (K200042)	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 System is used for human tissue vaporization,coagulation in dermatoloty and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	The CO2 Laser System is used for human tissue vaporization,coagulation in dermatoloty and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	SE

Tab 2 Performance Comparison

Item	Proposed Device		Predicate Device (K200042)		Remark
Maximum Power	30W		30W		SE
Work Mode	Surgery (Single Pulse, Continuous, Pulse)		Surgery (Single Pulse, Continuous, Pulse)		SE
Wavelength	10.6 um		10.6 um		SE
Beam Delivery	7 joint light guide arm		7 joint light guide arm		SE
Aiming Beam	Red indicator light (650nm, ≤5 mW)		Red indicator light (650nm, ≤5 mW)		SE
Spot Size	0.5 mm		0.5 mm		SE
Output Power	pulse	1-30W	pulse	1-30W	SE
	single	1-30W	single	1-30W	
	continuous	1-30W	continuous	1-30W	
Pulse Duration	Single Pulse Mode: 1-1000 ms Pulse mode: 1-1000 ms		Single Pulse Mode: 1-1000 ms Pulse mode: 1-1000 ms		SE
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		Closed inner circulating water cooling		Similar
Cleaning Method	70% isopropyl alcohol		70% isopropyl alcohol		SE
Dimension	39cm*45cm*117cm		37.5 cm x 29 cm x 113 cm		Analysis
Weight	44.83Kg		40kg		Analysis
Power input	AC 110V 60Hz		110V 60Hz or 230V 50Hz		SE

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 difference between proposed device and predicate device lies in the appearance(dimension, weight) . The difference will not affect the safety and effectiveness of proposed device in comparison to the predicate.

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 K200042.