March 3, 2026

Haidari Beauty Technology (Beijing) 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: K253920
Trade/Device Name: CO2 Laser Treatment Machine (CFR3M1)
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: November 18, 2025
Received: December 8, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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: 2026.03.03 11:54:40 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253920

Device Name
CO2 Laser Treatment Machine (CFR3M1)

Indications for Use *(Describe)*
The CO2 Laser Treatment Machine 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.

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510(k) Summary #K253920

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.

The assigned 510(k) Number: K253920

1. Date of Preparation: 2025/11/18

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: CO2 Laser Treatment Machine
Common Name: Powered Laser Surgical Instrument
Model(s): CFR3M1

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

5. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K200042
Product Name: CO2 Laser System
Manufacturer: Beijing Superlaser Technology Co., Ltd.

Reference Device
510(k) Number: K202250
Product Name: Dermatological Carbon Dioxide Laser Systems
Manufacturer: Zhuolu Jontelaser Manufacturing Technology Co., Ltd.

6. Device Description:

The device emits CO2 laser at the wavelength of 10.6μm, which is the spectral line in the far infrared range. The device is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

Carbon dioxide laser 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. Cutting, vaporization, carbonization, solidification and irradiation. 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:

The CO2 Laser Treatment Machine is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery,gynecology, podiatry,dental and otorhinolaryngology.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	**Proposed Device**	**Predicate Device K200042**	**Reference Device K202250**	**Remark**
Device Name	CO2 Laser Treatment Machine	CO2 Laser System	Dermatological Carbon Dioxide Laser Systems	/
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	SAME
Product Code	GEX	GEX	GEX	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	II	II	II	SAME
Indication for Use	The CO2 Laser Treatment Machine is used for human tissue vaporization, coagulation in dermatology 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.	The Dermatological Carbon Dioxide Laser System is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	SAME

Table 2 Performance Comparison

Item	**Proposed Device**		**Predicate Device K200042**		**Reference Device K202250**		**Remark**
Laser Type	CO2		CO2		CO2		SAME
Maximum Power	30W		30W		30W		SAME
Work Mode	Surgery (Single , Continuous, Pulse)		Surgery (Single Pulse, Continuous, Pulse)		CW Mode (Continuous Mode) P Mode (Muti-Pulse)		SAME
Laser Wavelength	10.6μm		10.6μm		10.6μm		SAME
Beam Delivery	Articulated arm		Articulated arm		7 joint Light guide arm		SAME
Spot Size	0.4mm		0.5 mm		0.4 mm		Analysis 1
Aiming Beam	Red semiconductor indicator light (650nm,<390μw)		Red indicator light (650nm, ≤5 mW）		650nm		SIMILAR
output power	pulse	1-30W	pulse	1-30W	pulse	1-30W	SAME
	single	1-30W	single	1-30W	——	——	SAME
	continuous	1-30W	continuous	1-30W	continuous	1-30W	SAME
Pulse Duration	Single Mode: 1-1000 ms Pulse mode: 1-1000 ms		Single Pulse Mode: 1-1000 ms Pulse mode: 1-1000 ms		Pulse mode: 1-1000 ms		SAME

Control System	LCD Touch screen, footswitch	Touch screen, footswitch	Touch screen, footswitch	SAME
Laser operation	Footswitch	Footswitch	Footswitch	SAME
Cooling System	Inner air circulation system	Closed inner circulating water cooling	Air cooling	SIMILAR
Power Supply	100V~240V 50-60Hz	110V 60Hz or 230V 50Hz	AC 100-240v~ ，50/60Hz	Analysis 2
Dimension	42cm *50cm* 132cm(without Articulated arm)	37.5 cm x 29 cm x 113 cm	52cm*40cm*125cm	
Weight	58kg	40kg	65Kg	

Analysis：

Analysis 1:

The proposed device has a spot size of 0.4 mm. Reference device (K202250) with an identical spot size and comparable energy-related specifications has been identified to support substantial equivalence.

The proposed device and reference device K202250 share the same laser type (CO_2), wavelength (10.6 μm), maximum output power (30 W), the same maximum pulse setting (1000ms), operating modes (continuous and pulse mode), and beam delivery method. Because the spot size and corresponding spot area are the same, the energy density delivered to tissue is directly comparable between the two devices.

Therefore, the spot size of the proposed device does not introduce new questions of safety or effectiveness, and the proposed device is substantially equivalent to the predicate devices.

Analysis 2:

The proposed device is different in Dimension and Weight from the predicate device. However, the dimension and weight difference are just in physical specification and this difference will not raise any issues in safety and effectiveness. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted. Therefore, this difference will not affect safety and effectiveness of the proposed device.

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Table 3 Safety Comparison

Item	**Proposed Device**	**Predicate Device K200042**	**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	SAME
EMC	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	SAME
Patient Contact Materials and Biocompatibility			
Cytotoxicity	No Cytotoxicity	/	SAME
Sensitization	No evidence of sensitization	/	SAME
Irritation	No evidence of irritation	/	SAME

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 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 Tests
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements
- 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
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- 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

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device (K200042).