March 28, 2026

Sanhe Meditech 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: K260257
Trade/Device Name: CO2 Laser System
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 27, 2026
Received: January 28, 2026

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.03.28 20:25:23 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260257

Device Name
CO2 Laser System

Indications for Use *(Describe)*
The 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
PRAStaff@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."

510(k) Summary #K260257

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

The assigned 510(k) Number: K260257

1. Date of Preparation: 1/15/2026

2. Sponsor

SANHE MEDITECH CO.,LTD.
#15 Building, Zhongnan High-tech Industrial Park, Liushan Street, Yanjiao, Sanhe, Hebei,065201,China

Contact Person: Song Xiaoxia
Position: General Manager
Tel: ＋86-010-61594366
Email: info@golden-laser.org

3. Submission Correspondent

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, China, 102401
Contact Person: Ray Wang
Position: General Manager
Tel: +86-18910677558
Email: information@believe-med.com

4. Proposed Device Identification

Device Name: CO2 Laser System
Common Name: Powered Laser Surgical Instrument
Model(s): GL066

Regulatory Information:
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number: 21 CFR 878.4810
Regulatory Class: II
Product Code: GEX

Review Panel: General & Plastic Surgery

Indications For Use:

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

5. Device Description

The working principle of CO2 laser system instrument is that the laser power supply drives the laser emitter to emit light, through the refraction of several mirrors, the light is transmitted to the treatment head, and then the light is aggregated into one point by the focusing mirror, which can reach a very high temperature, so that the treatment area can be sublimated into gas in an instant, so as to achieve the purpose of treatment.

The CO2 laser system comprises essential components including the main unit, treatment handpiece, foot switch, and various accessories. The wavelength of CO2 laser system is 10600nm.

6. Predicate Device Identification

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

7. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the subject device met all design specifications and to support device safety and effectiveness. The test results demonstrated that the subject device complies with the following standards:

- IEC 60601-1: 2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2020 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
- ISO 10993-5: 2009 Biological evaluation of medical device - 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

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	**Subject Device**	**Predicate Device K200042**	**Remark**
Device name	CO2 Laser System	CO2 Laser System	/
Model	GL066	SL-LC01	/
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	Same
Classification	II	II	Same
Product Code	GEX	GEX	Same
Indications for use	The CO2 Laser System 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 dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	Same
Maximum Power	30W	30W	Same
Work Mode	Surgery (Single Pulse, Continuous, Pulse)	Surgery (Single Pulse, Continuous, Pulse)	Same
Wavelength	10.6 um	10.6 um	Same
Beam Delivery	Articulated arm with 7-joint with 360 degree rotating	7 joint light guide arm	Same
Aiming Beam	Red indicator light(650nm)	Red indicator light (650nm)	Same
Spot size	0.5mm	0.5mm	Same
Output Power	Single Pulse:1-30w	Single Pulse:1-30w	Same
	Muti-Pulse:1-30w	Muti-Pulse:1-30w	
	Continuous:1-30w	Continuous:1-30w	
Pulse Duration	1-1000ms	1-1000ms	Same

Control System	Touch screen, footswitch	Touch screen, footswitch	Same
Laser Operation	Footswitch	Footswitch	Same
Laser medium/energy source	CO2	CO2	Same
Cooling System	Air cooling	Closed inner circulating water cooling	Similar
Cleaning Method	70% isopropyl alcohol	70% isopropyl alcohol	Same
Dimension	64x51x122cm	37.5 cm x 29 cm x 113 cm	Different
Weight	65kg	40kg	
Power input	110V 50Hz/60Hz	110V 60Hz or 230V 50Hz	Same
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No evidence of sensitization	No evidence of sensitization	Same
Irritation	No evidence of irritation	No evidence of irritation	Same
Electromagnetic compatibility and electrical safefy compliance	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	Same

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.

10. 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 or better than the legally marketed device (K200042).