May 7, 2026

Nanjing Bestview Laser S&T Co.,Ltd.
Wang, Jing
Management Representative
Contact Address

Re: K260974
Trade/Device Name: CO2 Laser Machine
Models: Monica-I, Monica-II
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: March 24, 2026
Received: March 24, 2026

Dear Wang, Jing:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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: 2026.05.07 16:50:04 -04'00'

Tanisha L. 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)*
K260974

Device Name
CO2 Laser Machine
Models: Monica-I, Monica-II

Indications for Use *(Describe)*
The CO2 Laser Machine is used for body soft tissue vaporization and coagulation in dermatology and plastic surgery, general surgery, gynecology.

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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Executive Summary

1. Submitter's Identification

Owner’s Name:	Nanjing Bestview Laser S&T Co.,Ltd.
Address:	1st&2nd Floor, Building5, Area1, Phase2, Liandong U Valley Science and Technology Innovation Park, No.1Hengyi Road, Nanjing Economic and Technological Development Zone, Nanjing 210000, Jiangsu, P.R. China
Phone:	+86-15824831075
E-mail:	jingwang@bestviewlaser.com
Contact:	Wang Jing
Date Prepared:	2026-04-04

2. Name of the Device

- **Trade/Proprietary Name :** CO2 Laser Machine
- **Common Name :** Powered Laser Surgical Instrument
- **Model :** Monica-I, Monica-II
- **Classification :** II
- **Product Code:** GEX

3. Device Description

The CO2 Laser Machine generate a 10,600nm wavelength, which is absorbed by water in the tissue.

The laser energy heats up the water until it reaches a boiling point causing the evaporation of the affected tissue. Some heat is absorbed by tissue adjacent to the ablated target area, causing tissue coagulation which induces hemostasis (the cessation of bleeding) as well as thermal stimulation of deep skin layers, which induces fibroblast stimulation and neocollagenesis (the formation of new collagen).

4. Indication for Use

The CO2 Laser Machine is used for body soft tissue vaporization and coagulation in dermatology and plastic surgery, general surgery, gynecology.

5. Technological Characteristics of Device as to Compare to the Predicate Device

Item	Proposed Device	Predicate Devices	Remark
Trade Name	CO2 Laser Machine	CO2 Laser Therapy System	/
Model	Monica-I&Monica-II	HS-411	/
510(k) Number	/	K201109	/
Product Code	GEX	GEX	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	Same
Class	II	II	Same
Intended Use	The CO2 Laser Machine is used for body soft tissue vaporization and coagulation in dermatology and plastic surgery, general surgery, gynecology.	The CO2 Laser Machine is used for body soft tissue vaporization and coagulation in dermatology and plastic surgery, general surgery, gynecology.	Same
Where Used	Hospital	Hospital	Same
Laser Type	RF tube laser	RF Sealed-off CO2	Same
Wavelength	10600nm	10600nm	Same
Aiming Beam Wavelength	635nm/≤390μw /Diode Laser (Red)	650nm/<2mw/Semiconductor Laser LD	Analysis1
Light delivery system	Articulated arm	Articulated arm	Same
Emission Control	Foot switch	Foot switch	Same
Laser Classification	Class IV	Class IV	Same
Software	Yes	Yes	Same
User Interface	LCD color touch screen	LCD color touch screen	Same
Operation Mode	● Fractional mode ;	● Fractional mode ;	Analysis2

	● normal mode (CW, Single, Repetitive, U. pulse) ;		● normal mode (CW, Single, Pulse, S. pulse, U. pulse) ; ● Vaginal mode;		
Output Power	1~30W		1~35W		Analysis3
Pulse Energy (Fractional)	3~300mJ/dot		1~300mJ/dot		Analysis4
Pulse Duration (Fractional)	0.1~10 ms		0.1~50 ms		In Range
Pulse Duration	Single	1-100ms	Single	10-500ms	Analysis5
	Repetitive	1-100ms	Pulse	5-500ms	
	Ultra	0.1-0.9ms	Ultra	0.1-0.9ms	
	CW	/	CW	/	
Pulse Interval	Single	/	Single	/	
	Repetitive	1-100ms	Repetitive	1-500ms	
	Ultra	1-100ms	Ultra	1-100ms	
	CW	/	CW	/	
Spot Size (Fractional)	150μm		150μm		Same
Spot Density(DPA)/cm^2	16-2500 dots		25-3025 dots		Analysis6
Scan Area Size	1x1mm~20x20mm		2x2mm~20x20mm		Analysis7
Patient Contact Sites	Intact skin		Intact skin		Same
Power Supply	AC 100-240V,50/60Hz		AC100V/240V,50/60Hz		Same

6. Comparison Summary

6.1 Discussion of Similarities and Differences

The features of the CO2 Laser Machine are compared to predicate devices in the form of above tables.

Our device and the predicate device differ in the following areas.

- **Analysis 1: Aiming Beam**

The aiming beam power and wavelength differ between the proposed device and the predicate device. As the aiming beam serves solely as a visible indicator, variations

in power only influence its brightness, while differences in wavelength—both falling within the visible red light spectrum—represent only a minor spectral shift. The difference will not affects the safety or effectiveness of the device.

- **Analysis 2: Operation Mode**

Although the predicate device has additional vaginal treatment modes and S. pulse compared with Proposed device, the difference will not affects the safety or effectiveness of the device.

- **Analysis 3: Output Power**

The output power range of the predicate device covers the output power range of the proposed device. That is the maximum output of proposed device will not affects the safety or effectiveness of the device.

- **Analysis 4:Pulse Energy**

The fractional pulse energy range of the predicate device covers the fractional pulse energy range of the proposed device. It will not result in a negative effect on safety and effectiveness.

- **Analysis 5: Pulse Interval/Duration**

Although the minimum pulse duration and the pulse interval of the proposed device are slightly lower than those of the predicate device, the maximum pulse duration and the pulse interval of the proposed device are within the corresponding range of the predicate device. The difference does not result in a negative effect on safety and effectiveness.

- **Analysis 6: Spot Density**

Although the proposed device's maximum and minimum spot densities are both lower than those of Predicate Device, but it overlaps with the spot density range of the predicate devices in a large part, and the difference does not result in a negative effect on safety and effectiveness.

- **Analysis 7: Scan Area Size**

The minimum scan area size of the proposed device is different from that of

predicate device, the scan area size of the predicate device is within the corresponding range of the proposed device.

The scan area size is only for Fractional Graphic area,the slightly device does not result in a negative effect on safety and effectiveness.

6.2 Argument for Substantial Equivalence to Predicate Devices

All above is the comparison between the CO2 Laser Machine (Model: Monica-I&Monica-II) and legally marketed device, which shows the proposed device and the predicate device are substantially equivalent.

7. Biocompatibility

The CO2 Laser Machine have been evaluated in accordance with Part 10993 of the International Standard Organization (ISO). Standard tests administered include:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10 2021, Biological Evaluation of Medical Devices - Part 10: Tests for Skin sensitization.
- 10993-23: 2021, Biological Evaluation of Medical Devices - Part 23: Tests for irritation.

8. Summary of Non-clinical Performance Tests

- ANSI AAMI ES60601-1: 2005&A1:2012 &A2:2021: Medical Electrical Equipment - Part 1: General Requirement for Basic Safety and Essential Performance;
- IEC 60601-1-2: 2014+A1:2020, Medical Electrical Equipment - Part 1-2: General Requirement for Basic Safety and Essential Performance- Collateral Standard: Electromagnetic Disturbances- Requirements and Tests;
- IEC TS 60601-4-2:2024, Medical electrical equipment -Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems;

- 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

9. Conclusion

From the comparison above, we have demonstrated that the CO2 Laser Machine (Model: Monica-I&Monica-II) has the same intended use, similar technological characteristics as the predicate device. Moreover, non-clinical testing contained in this submission demonstrated that any difference in their technological characteristics does not raise any new issues of safety and effectiveness.

In conclusion, the CO2 Laser Machine (Model: Monica-I&Monica-II) is substantial equivalent to the predicate device.