June 9, 2025

Nanjing Bestview Laser S&T Co., Ltd.
Jing Wang
Management Representative
1st & 2nd Fl, Bldg 5, Area 1, Phase 2 Liandong U Valley
Science & Technology Innovation Pk,No.1 Hengyi Rd,Nanjing Ec
Nanjing, Jiangsu 210000
China

Re: K250465
Trade/Device Name: CO2 Laser Machine (Lume)
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: May 13, 2025
Received: May 13, 2025

Dear Jing 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: 2025.06.09 14:19:43 -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

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)*
K250465

Device Name
CO2 Laser Machine (Lume)

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

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510(k) Summary # K250465

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

2. Name of the Device

- **Trade/Proprietary Name :** CO2 Laser Machine
- **Common Name :** Powered Laser Surgical Instrument
- **Model :** Lume
- **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 (Lume) 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 Devices

Item	Proposed Device	Predicate Device 1	Predicate Device 2	Remark
Trade Name	CO2 Laser Machine	CO2 Laser Therapy System	EdgeOne CO2 Laser	/
Model	Lume	HS-411	/	/
510(k) Number	K250465	K201109	K162169	/
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
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 Therapy System is used for body soft tissue vaporization and coagulation in dermatology and plastic surgery, general surgery, gynecology.	It is indicated for incision,excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology(ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.	Same
Where Used	Hospital	Hospital	Hospital	Same
Laser Type	RF tube laser	RF Sealed-off CO2	CO2	Same
Wavelength	10600nm	10600nm	10600nm	Same

Aiming Beam Wavelength	650nm/≤390μw /Diode Laser (Red)		650nm/<2mw/Semiconductor Laser LD		Diode laser(Red) 655 +/- 10nm, Max 1mW	Analysis1
Light delivery system	Articulated arm		Articulated arm		Articulated arm	Same
Emission Control	Foot switch		Foot switch		Foot switch	Same
Laser Classification	Class IV		Class IV		Class IV	Same
Software	Yes		Yes		Yes	Same
User Interface	LCD color touch screen		LCD color touch screen		LCD color touch screen	Same
Operation Mode	Fractional mode, normal mode (CW, Single, Repetitive, Ultra)		Fractional mode, normal mode and vaginal (CW, Single, Pulse, S. pulse, U. pulse)		Fractional mode, normal mode (CW, Pulse, Single Pulse, Repeat, Group pulse, Ultra)	Analysis2
Output Power	1~30W		1~35W		30W	Same
Pulse Energy	3~300mJ/dot		1~300mJ/dot		1~300mJ	Analysis3
Pulse Duration	Single	1-100ms	Single	10-500ms	1-1000ms	Analysis4
	Repetitive	1-100ms	Pulse	5-500ms		
	Ultra	0.1-0.9ms	U.pulse	0.1-0.9ms		
	CW	/	CW	/		
Pulse Interval	Single	/	Single	/		
	Repetitive	1-100ms	Pulse	1-500ms		
	Ultra	1-100ms	U.pulse	1-100ms		
	CW	/	CW	/		
Spot Size	300μm		150μm		120μm, 350μm, 800μm	Analysis5
Spot Density (DPA)/cm^2	12-400 dots		25-3025 dots		1-441 dots (350μm)	Analysis6
Intra-beam Distance	0.2-2.6mm		0.03-1.85mm		0.13-9.65mm	Analysis7
Scan Area Size	1x1mm~20x20mm		2x2mm~20x20mm		2x2mm~15mmx15mm	Analysis8
Power Supply	AC 110V/60Hz		AC100V/240V,50/60Hz		230V~, 50/60Hz, 500VA(max. laser output), 100 VA(stand by)	Same

6. Comparison Summary

6.1 Discussion of Similarities and Differences

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

The Proposed device and the predicate devices differ in the following areas.

- **Analysis 1: Aiming Beam**

The aiming beam power of the proposed device is different from that of the two predicate devices, and the aiming beam wavelength of the target device is same with the predicate device 1, similar to the predicate device 2. The aiming beam only serves as a red light indicator, different power only affects the brightness of red light, It has no impact on effectiveness and safety of the machine.

- **Analysis 2: Operation Mode**

Although the predicate device1 has additional vaginal treatment mode and S. pulse mode and the predicate device2 has additional pulse and Group pulse mode compared with Proposed device, the effectiveness and safety of other modes should not be affected.

- **Analysis 3:Pulse Energy**

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

- **Analysis 4: Pulse Interval/Duration**

Although the minimum pulse duration of the proposed device in partial mode are slightly lower than the predicate device1 but the maximum pulse duration and the pulse interval of the proposed device is within the corresponding range of the predicate device1,and the pulse duration and the pulse interval of predicate device2 cover the proposed device’s pulse duration and pulse interval, so the difference does not result in a negative effect on safety and effectiveness.

- **Analysis 5: Spot Size**

Although there is a certain difference in the spot size between proposed device and the predicate devices, the spot size of proposed device is between the predicate device1 (150μm) and predicate device 2 (350μm), so this difference will 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 1, the spot density per unit area is somewhat different due to the larger spot size used in the proposed device, that is, the area covered by a single dot is larger; while compared to the spot density of predicate device 2, the spot density of the prediction device 2 cover the proposed device's spot density, meanwhile the point size of them is similar. This suggests that our device performs similarly to predicate Device 2, and slight differences in spot density from the predicate device2 will not affect safety and effectiveness.

- **Analysis 7: Intra-beam Distance**

Although the intra-beam distance of the proposed device have some difference from that of the two predicate devices, but it overlaps with the intra-beam distance range of the two predicate devices in a large part, and the intra-beam distance range of the predicate device2 completely covers the intra-beam distance range of the proposed device, so the different will not adversely result in a negative effect on safety and effectiveness.

- **Analysis 8: Scan Area Size**

The minimum scan area size of the proposed device is different from that of the two predicate devices, the scan area size of the predicate devices 1 is within the corresponding range of the proposed device and the maximum scan area size of proposed device is same with the predicate devices 1 , the scan area size is only for Fractional Graphic area,the slightly different 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: Lume) and legally marketed devices, which shows the proposed device and the predicate devices are substantially equivalent.

7. Biocompatibility

The CO2 Laser Machine (Model: Lume) 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 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: Lume) has the same intended use, similar technological characteristics as the predicate devices. 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: Lume) is substantial equivalent to the predicate devices.