September 26, 2025

Nanjing Bestview Laser S&T Co., Ltd.
Jing Wang
Management Representative
1st & 2nd Floor, Building 5, Area 1, Phase 2 Liandong U
Vly Science and Tech Innovation Pk, No.1 Hengyi Rd
Nanjing, Jiangsu 210000
China

Re: K251919
Trade/Device Name: Thulium Laser System (Deluxlase)
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: June 23, 2025
Received: June 23, 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: 2025.09.26 10:27:03 -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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251919

Please provide the device trade name(s).

Thulium Laser System (Deluxlase)

Please provide your Indications for Use below.

Deluxlase is indicated for use in dermatological procedures requiring coagulation of soft tissue, treatment of actinic keratosis and treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251919

510(k) Summary

Prepared on: 2025-06-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Nanjing Bestview Laser S&T Co., Ltd.
Applicant Address	1st & 2nd Floor, Building 5, Area 1, Phase 2, Liandong U Valley Science and Technology Innovation Park, No.1 Hengyi Road, Nanjing Economic and Technological Development Zone, Nanjing 210000, Jiangsu, P.R. China Nanjing Jiangsu 210000 China
Applicant Contact Telephone	+86-15824831075
Applicant Contact	Ms. Jing Wang
Applicant Contact Email	jingwang@bestviewlaser.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Thulium Laser System (Deluxlase)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code(s)	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223727	Lavieen	GEX

Device Description Summary

21 CFR 807.92(a)(4)

Thulium Laser System is a thulium laser, producing a pulsed beam of coherent near-infrared light (1927 nm) upon activation by a footswitch. The beam is then directed to the treatment zone by means of an optical fiber coupled to a handpiece. An integrated LED touch screen gives the user control over the necessary laser system parameters. The Thulium Laser System is equipped with a 650 nm aiming beam.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Deluxlase is indicated for use in dermatological procedures requiring coagulation of soft tissue, treatment of actinic keratosis and treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the proposed device are the same as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device has no difference in significant technological characteristics such as wavelength, max pulse power and pulse width with the predicate device. There are only slight differences in scan area size, machine size and weight which are unimportant and can not result in a negative effect on safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Nonclinical Tests:
(1) EMC (2) Electrical, Mechanical, and Thermal
(3) Biocompatibility: Cytotoxicity, Irritation, Sensitization (4) Bench testing
Recognized Consensus Standards:
(1) IEC 60601-1: 2005(R)2012; (2) IEC 60601-2-22:2019; (3) IEC 60601-1-2: 2020; (4) IEC 60825-1:2014; (5) ISO 10993-5:2009; (6) ISO 10993-10: 2021; (7) ISO 10993-23: 2021

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device