April 20, 2026

Nanjing Bestview Laser S&T Co., Ltd.
Jing Wang
Management Representative
1st & 2nd Floor, Bldg. 5, Area 1, Phase 2, Liandong U
Valley Science & Technology Innovation Park, #1 Hengyi Rd.
Nanjing Economic & Technological Development Zone, Nanjing, Jiangsu 210000
China

Re: K260153
Trade/Device Name: Q-Switched Nd: YAG Laser System (Glamor Q)
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 20, 2026
Received: January 20, 2026

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 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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.04.20 14:13:29 -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

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.	K260153

Please provide the device trade name(s).

Q-Switched Nd: YAG Laser System (Glamor Q)

Please provide your Indications for Use below.

The Q-Switched Nd:YAG Laser System is indicated for the treatment of: benign cutaneous lesions, such as warts, scars, striae, and psoriasis; benign pigmented lesions, including lentigines, nevi, and birthmarks; and the removal of black and/or blue tattoos.

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

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

510(k) #:K260153

510(k) Summary

Prepared on: 2026-01-18

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	Q-Switched Nd: YAG Laser System (Glamor Q)
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
K193464	ND: YAG Laser	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The laser system utilizes established nanosecond laser technology, with a pulse duration in the range of 5 to 8 ns. At this pulse duration, the concentrated laser energy (reaching up to 1000 mJ at 1064nm and 500 mJ at 532nm) is rapidly absorbed by the target chromophores, such as melanin in pigmented lesions. The primary mechanism of action is selective photothermolysis. The absorbed energy is converted into heat, causing instantaneous and localized thermal expansion, vaporization, and coagulation of the target structures. Because the pulse duration is shorter than the thermal relaxation time of the surrounding tissue, the thermal damage is confined primarily to the intended targets, minimizing collateral damage. For epidermal pigmentation, the disrupted target material forms fine debris, which is subsequently eliminated through natural epidermal exfoliation or crusting. For deeper dermal targets, such as tattoo ink particles, the laser energy fragments them into minute particles. These fragments are then recognized and engulfed by the body's macrophages. Finally, they are cleared from the body via the lymphatic circulation. As a result, the pigmented lesions gradually fade and are cleared over time following the treatment.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Q-Switched Nd:YAG Laser System is indicated for the treatment of: benign cutaneous lesions, such as warts, scars, striae, and psoriasis; benign pigmented lesions, including lentigines, nevi, and birthmarks; and the removal of black and/or blue tattoos.

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 output energy and pulse width with the predicate device. There are only slight differences in 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 and Bench testing
(1) ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical Electrical Equipment - Part 1: General Requirement for Basic Safety and Essential Performance;
(2) 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;
(3) IEC TS 60601-4-2 Edition 1.0 2024-03 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems;
(4) IEC 60601-2-22 Edition 4.0 2019-11 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical cosmetic therapeutic and diagnostic laser equipment;
(5) IEC 60825 Edition 3.0 2014-07 Safety of laser products - Part 1: Equipment classification and requirements;
Biocompatibility: Cytotoxicity, Irritation, Sensitization
(6) ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity;
(7) ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization;
(8) ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation;
(9) IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes.

Conclusion
The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K193464