June 12, 2025

Beijing Sano Laser S&T Development Co.,Ltd
Zhu Qi
Manager
Room 7-201,No.1,Caida 3rd Street,Nancai Town
Shunyi District
Beijing,
China

Re: K250936
Trade/Device Name: Q-Switched Nd:YAG Laser (SHE-LSP101-1)
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 28, 2025
Received: March 28, 2025

Dear Zhu Qi:

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: 2025.06.12 15:50:00 -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)*
K250936

Device Name
Q-Switched Nd:YAG Laser (SHE-LSP101-1)

Indications for Use *(Describe)*
The Q-Swithched Nd:YAG Laser is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for for General Dermatology, Dermatologic and General Surgical Procedures as follows:
1064nm:
-Tattoo removal
dark ink: blue and black
-Treatment of Benign Pigmented Lesions
Nevus of ota
532nm:
-Tattoo removal
Light ink: red, sky blue and green.
-Treatment of benign vascular lesions
Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi.
-Treatment of benign pigmented lesions
Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.

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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"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) #: **K250936**

510(k) Summary

Prepared on: 2025-05-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Beijing Sano Laser S&T Development Co.,Ltd
Applicant Address	Room 7-201,No.1,Caida 3rd Street,Nancai Town,Shunyi District Beijing N/A N/A China
Applicant Contact Telephone	+86 10 57150601
Applicant Contact	Mrs. Zhu Qi
Applicant Contact Email	2881494813@qq.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Q-Switched Nd:YAG Laser (SHE-LSP101-1)
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
K123293	PASTELLE Q-SWITCHED ND: YAG LASER	GEX
K014234	Medlite C6 Q-Switched Nd:YAG Laser	GEX

Device Description Summary

21 CFR 807.92(a)(4)

Device Description

Nd:YAG laser is a type of solid laser that is stimulated through Yttrium Aluminum Garnet (YAG Crystal) doped with a very small amount of Neodymium (Nd). Nd:YAG laser can generate pulsed or continuous laser, emitting laser with specific wavelength (usually 532nm or 1064nm). The principle of Nd:YAG laser product is that electrons in atoms can absorb energy and change from a lower energy level to higher energy level, then these electrons fall back to the lower energy level, releasing energy in the form of photons. Compared with ordinary light source, laser is monochromatic, directional and brighter.

Q-Switched Nd:YAG Laser is a multi-wavelength, pulsed laser system designed for the treatment of benign pigmented lesions. The device can produce two wavelengths, 1064nm and 532nm, to treat different skin color. It consists of control panel module, main control module, laser power module, temperature and humidity control module and laser module. The physician is able to select the desired wavelength and the related output energy via control panel.

Machine System

Q-Switched Nd:YAG Laser (hereinafter referred to as “Machine”) consists of machine main body (including Laser Device, Transmission and Target Indicating Device, Laser Power Supply and Control System, Safety Protection System, Cooling System, Power Supply System, Control System), 7-Joint Laser Arm, Vari-Focusing Handpiece, Foot Switch, Laser Protective Glasses, Power Cable, Support Bar (A Group of Support Bar and 2 Support Clamps), Casters and Attached Machine Accessories, etc. As shown by Figure 1, the machine shell is ABS shell, its accessories are aluminum alloy parts.

Performance

Laser Peak Wavelength 1064nm & 532nm, ±5nm;

Spot Size
For 1064nm: 3mm, 4mm, 6mm, 8mm, ≤±20%
For 532nm: 3mm, 4mm, 6mm, ≤±20%

Laser Pulse Energy:
For 1064nm, Laser Pulse Energy is 200~900mJ adjustable, Step 20mj, ≤ ±20%; For 532nm, Laser Pulse Energy is 50~500mJ adjustable, Step 10mj, ≤ ±20%;

Max Fluence:
For 1064nm, 12.74J/cm2.
For 532nm, 7.08J/cm2

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Q-Swithched Nd:YAG Laser is indicated for use in tattoo removal, treatment of benign vascular lesions, treatment of benign pigmented lesions, incision, excision, ablation, vaporization of soft tissue for for General Dermatology, Dermatologic and General Surgical Procedures as follows:
1064nm:
-Tattoo removal
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Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi.
-Treatment of benign pigmented lesions
Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Q-Switched Nd:YAG Laser incorporates the intended use of Primary predicate device and the intended use of Secondary predicate device, and the treatment functions of each wavelength are detailed based on the wavelength classification. Under the premise of unchanged original meaning, the description of intended use is more scientific, precise and correct. In summary, the indication for use of the devices(Q-Switched Nd:YAG Laser\Primary predicate device\Secondary predicate device) are the same.

Technological Comparison 21 CFR 807.92(a)(6)

The device has the similar technological characteristics as primary predicate device or secondary predicate device in wavelength, laser type, laser classification, pulse width and spot size. The minor difference in energy density is within the range of the predicates and would not raise any safety and effectiveness issues.

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

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:
• IEC 60601-1 Edition 3.2 2020-08, Medical electrical device Part1: General requirements for basic safety and essential performance
• IEC 60601-1-2, Edition 4.1 2020-09, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
• IEC 60601-2-22, Edition 3.1 2012-10 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
• IEC/TR 60601-4-2, 2016, Medical electrical equipment - Par4.2: Guidance and interpretation - electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
• IEC 60825-1, Edition 2.0 2007-03, Safety of laser products -Part 1: Equipment classification and requirements
• ISO 10993-5, hird edition 2009-06-01, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
• ISO 10993-10, Fourth edition 2021-11, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
• ISO 10993-23, First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation
Clinical study is not applicable.
Conclusions: Based on the performance testing and validation studies, the subject device is substantially equivalent to the predicate devices.