August 11, 2026

Beijing Nubway S&T Co., Ltd.
℅ Lena Zhang
RA Manager
Tianjin Xinnuocheng Medical Technology Co., Ltd.
Rm. 1505, Wanhai Bldg., Dazhigu Sub-District
Hedong District
Tianjin, 300170
China

Re: K261841
Trade/Device Name: Q Switched Nd:YAG Laser machine (QLQW-01)
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 2, 2026
Received: June 3, 2026

Dear Lena Zhang:

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: 2026.08.11 16:53:46 -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.	K261841

Please provide the device trade name(s).

Q Switched Nd:YAG Laser machine (QLQW-01)

Please provide your Indications for Use below.

The Q Switched Nd:YAG Laser machine 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 general dermatology as follows:
1064nm:
-Tattoo Removal
Dark ink: blue and black.
-Treatment of Benign Pigmented Lesions
Nevus of ota.
532nm:
-Tattoo Removal
Light ink: red, Light ink: 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.

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

The assigned 510(k) Number: K261841

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Preparation: 2026/06/03

2. Sponsor Identification

Beijing Nubway S&T Co., Ltd.

202,No.5 workshop, No.1 caida 3rd Road Nancai Shunyi District, Beijing China. 101300.

Contact Person: Xiting Fan

Position: Registered Manager

Tel: +86-13716933250

Email: 1015932471@qq.com

3. Designated Submission Correspondent

Ms. Lena Zhang

Tianjin Xinnuocheng Medical Technology Co., LTD.

Room 1505, Wanhai Building, Dazhigu Sub-district, Hedong District Tianjin, Hedong 300170 CHINA

Tel: +86-13821206320

Email: ra@tianjinxinnuochengyi.com.cn

4. Identification of Proposed Device

Trade Name: Q Switched Nd:YAG Laser machine (QLQW-01)

Common Name: Powered Laser Surgical Instrument

Regulatory Information

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Classification: II

Product Code: GEX

Regulation Number: 878.4810

Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

Predicate device:
510(k) Number: K193609
Product Name: Q Switched Nd:YAG Laser machine
Manufacturer: Beijing Lead Beauty S & T Co., Ltd

Reference Device:
510(k) Number: K152856
Product Name: Helios III Q-Switched Nd:YAG Laser System
Manufacturer: Laseroptek Co. Ltd.

6. Device Description

The Q Switched Nd:YAG Laser machine is a multi-wavelength, pulsed laser system designed for dermatological treatments. The device can produce 1064nm and 532nm two different laser wavelengths for different dermatological treatments. It is composed of mainframe (including power supply system, control system and cooling system), treatment handpiece, treatment head, Pedal, power cord and other accessories. The physician is able to select the desired wavelength and the related output energy via control panel.

7. Indication For Use Statement:

The Q Switched Nd:YAG Laser machine 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 general dermatology as follows:

1064nm:

-Tattoo Removal

Dark ink: blue and black.

-Treatment of Benign Pigmented Lesions

Nevus of ota.

532nm:

-Tattoo Removal

Light ink: red, Light ink: 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.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device K261841	Predicate Device K193609	Reference Device K152856	Remark
Device name	Q Switched Nd:YAG Laser machine	Q Switched Nd:YAG Laser machine	Helios III Q-Switched Nd:YAG Laser System	/
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Classification	II	II	II	SAME
Product Code	GEX	GEX	GEX	SAME
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	SAME
Indications for use	The Q Switched Nd:YAG Laser machine 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 general dermatology as follows: 1064nm: -Tattoo Removal Dark ink: blue and black. -Treatment of Benign Pigmented Lesions Nevus of ota. 532nm: -Tattoo Removal Light ink: red, Light ink: sky blue and green. -Treatment of Benign Vascular Lesions Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi. -Treatment of Benign Pigmented Lesions	The Q-Switched Nd: YAG Laser Therapy System 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 general dermatology as follows: 1064nm: -Tattoo Removal Dark ink: blue and black. -Treatment of Benign Pigmented Lesions Nevus of ota. 532nm: -Tattoo Removal Light ink: red, Light ink: sky blue and green. -Treatment of Benign Vascular Lesions Port wine birthmarks; Telangiectasias; Spider angioma; Cherry angioma; Spider nevi. -Treatment of Benign	Incision, excision, ablation, vaporization of soft tissue for general dermatology (1064 nm) Removal or lightening of unwanted hair with or without adjuvant preparation (1064nm) Tattoo Removal: Dark ink (blue and black) (1064 nm) Tattoo Removal: light ink (red, sky blue, green) (532 nm) port wine birthmarks (532 nm) telangiectasias (532 nm) spider angioma (532 nm) cherry angioma (532 nm) spider nevi (532 nm) cafe-au-lait birthmarks (532 nm) solar lentiginos, senile lentiginos, becker's nevi, freckles, nevus spilus (532 nm) nevus of ota (1064 nm)	SAME with Predicate Device

	Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.	Pigmented Lesions Cafe-au-lait birthmarks; Solar lentiginos; Senile lentiginos; Becker's nevi; Freckles; Nevus spilus.		
Lamp Source	Xenon Lamp	Xenon Lamp	Xenon Lamp	SAME
Energy Source	ND:YAG	ND:YAG	ND:YAG	SAME
Wavelength	1064nm and 532nm	1064nm and 532nm	1064nm and 532nm	SAME
Maximum pulse energy	600mJ@1064nm 300mJ@532nm	500mJ for 1064nm 260mJ for 532nm	1.3 J (0.5J @ 532 nm) / pulse	Analysis(1)
Pulse Duration	7ns±2ns	6ns±1ns	10ns	Analysis(2)
Spot Size	1064nm:3mm 532nm:2.5mm	2-10mm	(1064) 5 mm (532) 4 mm (Collimator) 8 mm (Zoom) 1~7 mm	Analysis(3)
Repetition rate	1-10Hz	1-10Hz	1-10Hz	SAME
Aiming beam wavelength	635nm	635nm	Unknown	SAME with Predicate Device
Aiming laser output power	0.1mW-5mW	0.1mW-5mW	Unknown	SAME with Predicate Device
Laser output mode	Q-switched pulse	Q-switched pulse	Q-switched pulse	SAME
Fluence range	1064nm：2.8～8.49J/cm² 532nm：2.03～6.11J/cm²	1064nm 0.63-15.92J/cm^2 532nm 0.33-8.28 J/cm^2	1 – 8J/cm^2 @ 1 to 8 mm spot size	Analysis(4)
Patient contact material	Aluminum alloy	Aluminum alloy	Unknown	SAME with Predicate Device
Biocompatibility				
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Unknown	SAME with Predicate Device
Sensitization	No evidence of Sensitization	No evidence of Sensitization	Unknown	SAME with Predicate Device
Irritation	No evidence of Irritation	No evidence of Irritation	Unknown	SAME with Predicate Device
Electrical Safety and EMC				
Electrical Safety	Comply with IEC 60601-1	Conforms with IEC 60601-1	Unknown	SAME with Predicate Device
EMC	Comply with IEC 60601-1-2	Conforms with IEC 60601-1-2	Unknown	SAME with Predicate Device

Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Conforms with IEC 60601-2-22, IEC 60825	Unknown	SAME with Predicate Device

Analysis：

Analysis(1)

The Maximum pulse energy of the proposed device is similar with the predicate device, and within the reference device, and the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test, IEC 60825-1 test. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis(2)

The Pulse Duration of the proposed device is similar with the predicate device, and within the reference device, and the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test, IEC 60825-1 test. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis(3)

The Spot Size of the proposed device is within the predicate device, and similar with the reference device, and the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test, IEC 60825-1 test. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Analysis(4)

The Fluence range of 1064nm is within the predicate device and similar with the reference device, the fluence range of 532nm only has minor difference with the predicate device and the reference device, the difference will not affect the effectiveness and safety. And the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test, IEC 60825-1 test, the safety and performance of the product can be ensured.

9. Non-Clinical Test Conclusion

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:

- ISO 10993-5 Third 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 skin sensitization.
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation
- IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: 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 disturbances - Requirements and tests
- 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
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements
- IEC 60601-1-6 Edition 3.2 2020-07, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- Software Verification and Validation was conducted per FDA's guidance Content of Premarket Submissions for Device Software Functions (June 14, 2023), and basic documentation was provided.

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe and effective,as the legally marketed predicate device Q Switched Nd:YAG Laser machine (K193609).