



March 3, 2025

Beijing Nubway S&T Co., Ltd.
% Owen He
Consultant
Microkn Medical Technology Service (Shanghai) Co.,LtdCompany
Room 901, Huafa Center, 889 Pinglu Road, Jing 'an District
Shanghai, Shanghai 200040
China

Re: K242943

Trade/Device Name: Q Switched Nd:YAG Laser machine (QNHF-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: September 10, 2024
Received: September 25, 2024

Dear Owen He:

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: 2025.03.03
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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

510(k) Number (if known)

K242943

Device Name

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

Indications for Use (Describe)

The Q Switched Nd:YAG Laser machine (QNHF-01) 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

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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.

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

Prepared on: 2025-02-25

Contact Details[21 CFR807.92\(a\)\(1\)](#)

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Applicant Contact	Mr. Xiting Fan
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Correspondent Name	Microkn Medical Technology Service (Shanghai) Co.,LtdCompany
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Correspondent Contact Telephone	1+86 17721293816
Correspondent Contact	Mr. Owen He
Correspondent Contact Email	fda@microkn.com

Device Name[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Q Switched Nd:YAG Laser machine (QNHF-01)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgiical 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
K163123	Q-Switched Nd:YAG Laser Systems	GEX

Device Description Summary[21 CFR 807.92\(a\)\(4\)](#)

Q Switched Nd: YAG Laser machine (QNHF-01) is laser system which delivers laser at a wavelength 1064nm or 532nm. 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.

Intended Use/Indications for Use[21 CFR 807.92\(a\)\(5\)](#)

The Q-Switched Nd: YAG Laser machine (QNHF-01) 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

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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.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

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

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The proposed device has technological characteristics that are similar to the predicate device. Both devices have output wavelengths of 1064 nm and 532 nm, and both devices have treatment window diameter ranges of 2 - 10 mm. There is a difference of 1 nanosecond in the pulsewidth (6 ns for the proposed device vs 5 ns for the predicate) and the proposed device's maximum repetition rate of 10 Hz is greater than the predicate device's maximum repetition rate of 5 Hz. The proposed device's maximum 532 nm pulse energy is larger (260 mJ for the proposed device vs 250 mJ for the predicate). These differences however are not considered to raise new questions regarding safe and effective use of the device for the proposed indications for use.

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 CONSOLIDATED VERSION Medical electrical device Part1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION 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 60825-1 Edition 2.0 2007-03 Safety of laser products -Part 1: Equipment classification and requirements
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 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

No clinical study is included in this submission.

Based on the technological similarities and the results of performance testing conducted with the device, the device is considered to be substantially equivalent to the predicate device K163123.