



July 17, 2026

Beijing Nubway S&T Co., Ltd.
% Owen He
Consulant
Microkn Medical Technology Service (Shanghai)Co.,Ltd Company
Rm. 901, Huafa Center, 889 Pinglu Rd., Jing 'An District
Shanghai, Shanghai 200040
China

Re: K261693

Trade/Device Name: Diode laser hair removal machine (QDTM-04)
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: May 21, 2026
Received: May 22, 2026

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 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: 2026.07.17
16:47:54 -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.

K261693

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Please provide the device trade name(s).

?

Diode laser hair removal machine (QDTM-04)

Please provide your Indications for Use below.

?

The Diode Laser Hair Removal Machine is intended for hair removal permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

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](#))

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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)

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Beijing Nubway S&T Co., Ltd.
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Correspondent Contact	Mr. Owen He
Correspondent Contact Email	fda@microkn.com

Device Name

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

Device Trade Name	Diode laser hair removal machine (QDTM-04)
Common Name	Powered Laser Surgical Instrument
Classification Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
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
K242951	Diode laser hair removal machine (QDTM-02)	GEX

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The subject device is a diode laser system consisting of a main unit (housing a control panel, cooling system, circuit control system, and semiconductor laser power supply), treatment handpiece, and foot switch. Treatment is delivered via pulsed 808 nm light to achieve selective photothermolysis.

Intended Use/Indications for Use

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

The Diode Laser Hair Removal Machine is intended for hair removal permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

Indications for Use Comparison

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

The indication for use is the same with predicate devices.

Technological Comparison

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

Device & Predicate Device(s):	K261693	K242951
General Device Characteristics		
Product Code	GEX	GEX
Laser Type	Diode Laser	Diode Laser
Laser Classification	Class IV	Class IV
Wavelength	808 nm	808 nm
Spot Size	2.4 cm ² (1.2 x 2 cm)	Handpiece 1: 1.44 cm ² Handpiece 2: 4 cm ²
Energy Density	3.3-165.6 J 1.375-69 J/cm ²	Handpiece 1: 3.2-126.7 J 2.222-88 J/cm ² Handpiece 2: 4.7-234.1 J 1.175-58.525 J/cm ²
Pulse Width	10 – 200 ms	10 – 200 ms
Frequency	1-20 Hz	1-20 Hz

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 60601-1:2005+AMD1:2012+AMD2:2020 (including US National Differences) Medical electrical device Part1: General requirements for basic safety and essential performance
- IEC 60601-1-2 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 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 Medical electrical equipment - Part 4.2: Guidance and interpretation - electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60825-1 Safety of laser products -Part 1: Equipment classification and requirements
- ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software documentation level for this device was determined to be "basic".
- Testing was conducted to validate that the proposed device meets design specifications for wavelength, energy density, pulse width, spot size, and frequency.
 - o No clinical study is included in this submission.

Based on the data provided, we conclude that the subject device is as safe, as effective, and performs as well as the predicate device.