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U.S. FOOD & DRUG ADMINISTRATION

April 28, 2025

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

Re: K242951
Trade/Device Name: Diode laser hair removal machine (QDTM-02)
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 27, 2025
Received: March 27, 2025

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: 2025.04.28 14:47:19 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242951

Device Name
Diode laser hair removal machine (QDTM-02)

Indications for Use *(Describe)*
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.

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.

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510(k) Summary

Prepared on: 2025-04-22

Contact Details

21 CFR 807.92(a)(1)

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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-02)
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
K180353	Diode laser hair removal device	GEX
K192735	Diode Laser Hair Removal Machine	GEX
K223680	Eneka Pro	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The semiconductor laser therapeutic device is mainly composed of a host, the treatment handle, foot switch, power cord, and accessories. The host consists of a control panel, cooling system, circuit control system, semiconductor laser power

supply, etc.

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)

The "Diode Laser Hair Removal Machine" (Model QDTM-02) is demonstrated to be substantially equivalent to two predicate devices (Predicate Device 1: 510(k) No. K192735; Predicate Device 2: 510(k) No. K180353) through comprehensive comparisons.
In terms of general information, all three devices share the same Product Code (GEX), Regulation Number (21 CFR 878.4810), and Regulatory Class (Class II). Their indications for use are identical: intended for permanent hair reduction on all skin types (Fitzpatrick skin types I–VI, including tanned skin), with the same definition of "permanent hair reduction" (long-term stable reduction in regrown hairs measured at 6, 9, and 12 months after treatment completion). In configuration, they all include a main unit and handpiece; Predicate Device 1 and the proposed device both have a foot control, and all operate on the principle of a diode laser.
For performance parameters, the laser type, classification, and wavelength (all Class IV Diode Laser, 808nm) are completely identical. The proposed device's frequency (1–20Hz) matches that of Predicate Device 2, and its pulse duration (10–200ms) falls within the ranges of both predicate devices (50–400ms for K192735 and 10–400ms for K180353). Minor differences in power supply do not affect practical use or safety, and the dimensions are exactly the same as those of Predicate Device 1. In handpiece parameters, the small spot handpiece has an identical spot size (1.44 cm^2) to Predicate Device 2. While the large spot handpiece size of the proposed device (4 cm^2) differs from Predicate Device 1 (2.4 cm^2), it is very similar to the reference device (similar device) Eneka Pro (34x14mm, 4.75cm^2). The document analysis notes that this difference is within the safe and effective range—since the reference device is legally marketed and its spot size safety has been verified, the proposed device's difference does not exceed a reasonable scope and does not affect the determination of substantial equivalence.
In terms of safety, all three devices have undergone biocompatibility testing. Although the patient contact material of the proposed device differs from that of Predicate Device 2, test results comply with the ISO 10993 series standards. Electrical safety and EMC also meet relevant standards. In summary, despite minor differences in some parameter ranges, these differences either fall within the scope of the predicate devices or have been analyzed to not affect safety and effectiveness. Based on device comparison information and non-clinical testing, the proposed device is substantially equivalent to the two predicate devices.

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 Medical electrical device Part1: General requirements for basic safety and essential performance
• IEC 60601-1-2:2014 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
• IEC 60601-2-22:2019 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 - Par4.2: Guidance and interpretation - electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
• IEC 60825-1:2014 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 irritation and delayed-type hypersensitivity
• ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation

No clinical study is included in this submission.

The Diode Laser Hair Removal Machine (Model QDTM-02) is demonstrated to be substantially equivalent to two predicate devices.