June 6, 2025

Hebei JT Medical Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Services Co., Ltd.
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, Beijing 102401
China

Re: K250722
Trade/Device Name: Nd: YAG Laser Therapy System (QN-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 10, 2025
Received: March 10, 2025

Dear Ray Wang:

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: 2025.06.06 13:21:53 -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)*
K250722

Device Name
Nd: YAG Laser Therapy System (QN-1)

Indications for Use *(Describe)*
The Nd: YAG Laser Therapy System is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, Nevus, and Birthmark; and the removal of black or blue tattoos.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: **K250722**

1. Date of Preparation: 03/10/2025

2. Sponsor:

Hebei JT Medical Co.,Ltd.
C12 Hegu Industrial Park, Chaoyang Road, Development Zone, Zhuozhou City, Hebei Province, China, 072750
Contact Person: Ying Wang
Position: General Manager
Tel: +86-13910106157
Email: certification@jontelaser.com

3. Submission Correspondent:

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, China, 102401
Contact Person: Ray Wang
Position: General Manager
Tel: +86-18910677558
Fax: +86-10-56335780
Email: information@believe-med.com

4. Proposed Device Identification:

Trade Name: Nd: YAG Laser Therapy System
Common Name: Powered Laser Surgical Instrument
Model(s): QN-1

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument
Classification: II
Product Code: GEX

Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Review Panel: General & Plastic Surgery

Indication For Use Statement:
The Nd: YAG Laser Therapy System is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, Nevus, and Birthmark; and the removal of black or blue tattoos.

5. Device Description:

The Nd: YAG Laser Therapy System (Model: QN-1) is laser system which delivers laser at a wavelength 1064nm or 532nm and the pulse mode is single pulse.
In laser handpiece, there is one optical cavity containing the Nd:YAG crystal. The laser beam is directed to the treatment zone. When the laser beam contacts human tissue, the energy in the beam is absorbed, resulting in a very rapidly, highly localized temperature increase to the target tissue. The instantaneous temperature increase (thermal effect) causes the cells change of target tissue to achieve laser treatment effect.

6. Predicate Device Identification:

Predicate Device:
510(k) Number: K232716
Product Name: Q-Switched Nd:Yag laser
Manufacturer: Hebei Zhemai Technology Co., Ltd

7. 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:

- IEC 60601-1: 2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2020 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: 2019 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: 2007 Safety of laser products - Part 1: Equipment classification, and requirements
- ISO 10993-5: 2009 Biological evaluation of medical device - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- IEC TR 60601-4-2: 2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

8. Clinical Test Conclusion:

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison:

Table 1 Comparison

ITEM	**Proposed Device**	**Predicate Device (K232716)**	Remark
Product Code	GEX	GEX	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	2	2	SAME
Type of Use	Prescription Use	Prescription Use	SAME
Indications for use	The Nd: YAG Laser Therapy System is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, Nevus, and Birthmark; and the removal of black or blue tattoos.	The Q-switched laser therapy device is indicated for the treatment of: benign cutaneous lesions, such as Warts, Scars, Striae and Psoriasis; benign pigmented lesions, such as Lentigines, nevus, and birthmark; and the removal of black or blue tattoos.	SAME
Laser Medium	Nd:YAG	Nd:YAG	SAME
Wavelength	1064 nm; 532 nm	1064 nm; 532 nm	SAME
Output energy	100mj-1000mj for 1064nm 100mj-450mj for 532nm	100-1000mJ for 1064nm 50-500mJ for 532nm	Analysis 1
Max. Energy Density	1064nm: 31.8J/cm^2 532nm: 15.9 J/cm^2	31.8J/cm^2 for 1064nm 15.9 J/cm^2 for 532nm	SAME
Spot Size	2-10mm	2-10mm	SAME
Pulse Width	6ns	6ns	SAME
Disinfection	Arms without focusing lenses and probes can be disinfected with a 75% medical grade alcohol wipe.	Arms without focusing lenses and probes can be disinfected with a 75% medical grade alcohol wipe.	SAME

Laser Class	Class 4	Class 4	SAME
Cooling method for treated skin area	Closed water circulation	Closed water circulation	SAME
Aiming Beam	650nm (red) Aim at the light: 10mW	<6mW, 650nm (red) semiconductor aiming light	Analysis 2
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SAME

Analysis 1:

The proposed device only has slight difference in Output energy with the predicate device. The output energy of the proposed device is within the allowable error range of the predicate device, which can justify that the difference in the parameter of output energy will not raise new safety issues of the proposed device. And the bench tests conducted on the proposed device is same with the predicate device, the results of which could support the substantially equivalency with predicate device. So the slight difference is considered to have no effect on effectiveness and safety.

Analysis 2:

The Aiming Beam of the proposed device is different from the predicate device. However, the configuration difference are just in physical specification. The output intensity of the output device's red laser aiming beam is more that that of the predicate device. The intensity is adequate in order to provide feedback regarding the beam's location to the device user, the effectiveness of the proposed device is determined to be accepted. By complying with IEC 60601-1 and IEC 60825-1, the mechanical performance of the proposed device is determined to be accepted. Therefore, this difference will not affect safety and effectiveness of the proposed device.

10. Substantially Equivalent (SE) Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device (K232716).