



November 6, 2025

HEBEI KEYLASER SCI-TECH Co.,Ltd
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5,
YiHe North Rd., FangShan District
Beijing, 102401
China

Re: K252515

Trade/Device Name: Q-Switched Nd:Yag laser (K690)

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: August 11, 2025

Received: August 11, 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](https://www.fda.gov/training-and-continuing-education/cdrh-learn)) 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: 2025.11.06
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Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Office of Product Evaluation and Quality
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Enclosure

Indications for Use

510(k) Number (if known)
K252515

Device Name
Q-Switched Nd:Yag laser (K690)

Indications for Use (Describe)

The Q-Switch Nd:Yag laser is intended for use in removal of dark ink (black, blue and brown) tattoo, removal of benign dermal pigmented lesions including, but not limited to: Nevus of OTA, Common Nevi, and Melasma, removal or lightening of unwanted hair with or without adjuvant preparation, skin resurfacing procedures for the treatment of acne scars and wrinkles.

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.

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The assigned 510(k) Number: K252515

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: 11/04/2025
2. Sponsor Identification

HEBEI KEYLASER SCI-TECH Co.,Ltd

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Q-Switched Nd:Yag laser (K690)

Common Name: Powered Laser Surgical Instrument

Regulatory Information

Classification Name: Powered Laser Surgical Instrument

Classification: II

Product Code: GEX

Regulation Number: 878.4810

Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

510(k) Number: K202758

Product Name: Nd: YAG Laser Therapy Systems Model: HM-YL900

Manufacturer: Shangdong Huamei Technology Co., Ltd.

6. Device Description

Q-Switched Nd:Yag laser consists of a main engine, controller, power control switch, optical system and power input panel.. A multifunctional microcomputer can control and adjust the size of the laser spot, making it suitable for treating diseases in different parts of the body. Parameters such as the laser energy required for the treatment can be set by the user appropriately.

7. Indication For Use Statement:

The Q-Switch Nd:Yag laser is intended for use in removal of dark ink (black, blue and brown) tattoo, removal of benign dermal pigmented lesions including, but not limited to: Nevus of OTA, Common Nevi, and Melasma, removal or lightening of unwanted hair with or without adjuvant preparation, skin resurfacing procedures for the treatment of acne scars and wrinkles.

8. Substantially Equivalent (SE) Comparison

Tab 1 General Comparison

Item	Proposed Device	Predicate Device (K202758)	Remark
Product Code	GEX	GEX	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Class	2	2	SE
Where used	hospital	hospital	SE
Intended Use	<p>The Q-Switch Nd:Yag laser is intended for use in removal of dark ink (black, blue and brown) tattoo, removal of benign dermal pigmented lesions including, but not limited to: Nevus of OTA, Common Nevi, and Melasma, removal or lightening of unwanted hair with or without adjuvant preparation, skin resurfacing procedures for the treatment of acne scars and wrinkles.</p>	<p>The Nd: YAG Laser Therapy Systems is intended 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:</p> <p>532nm wavelength:</p> <ul style="list-style-type: none"> ● Removal of light ink (red, sky, blue, green, purple, and orange) tattoo ● Treatment of benign vascular lesions including, but not limited to: telangiectasias, ● Treatment of benign epidermal pigmented lesions including, but not limited to: cafe-au-lait, solar lentiginos, senile lentiginos, Becher's, nevi Freckles, Nevus spilus, Seborrheic Keratoses ● Treatment of Post Inflammatory Hyper-Pigmentation <p>1064nm wavelength:</p> <ul style="list-style-type: none"> ● Removal dark ink (black, blue and brown) tattoo ● Removal of benign dermal pigmented lesions including, but not limited to: Nevus of OTA, Common Nevi, and Melasma, ● Removal or lightening of unwanted hair with or without adjuvant preparation ● Skin resurfacing procedures for the treatment of acne scars and wrinkles 	<p>Same as 1064nm of predicate device</p>

Tab 2 Performance Comparison

Item	Proposed Device	Predicate Device (K202758)	Remark
Laser Medium	Nd:YAG	Nd:YAG	SE
Wavelength	1064 nm	1064 nm 532 nm	Similar
Aiming Beam Wavelength	650 nm	650 nm	SE
Output energy	1000mJ	1000mJ for 1064nm 500mJ for 532nm	Similar
Fluence	1.27 - 31.8 J/cm ²	1.27 - 31.8 J/cm ² for 1064nm 0.6 - 15.9 J/cm ² for 532nm	Similar
Spot Size	2-10mm	2-10mm	SE
Pulse Width	4ns-6ns	4ns-6ns	SE
Frequency	1-10 Hz ²	10 Hz Max.	SE
Laser Class	Class 4	Class 4	SE

Tab 3 Safety Comparison

Item	Proposed Device	Predicate Device K202758	Remark
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IC 60601-2-22	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825-1	Comply with IEC 60601-2-22, IEC 60825-1	SE

Analysis

The proposed device has only a wavelength of 1064 nm and the predicate device has two wavelengths of 1064 nm and 532 nm, but the intended use of the proposed device, the output energy and fluence are the same as those of the predicate device 1064 nm. And the spot size, pulse width and frequency are the same as those of the predicate device.

Based on the nonclinical tests performed, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device.

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:

- IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements

- IEC 60601-2-22: 2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- ISO 10993-10 Fourth edition 2021, 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
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- 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 Compatibility-Requirements And Test

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

Based on the non-clinical tests performed, the subject device is as safe, as effective, and performance as well as the legally marketed predicate device, Nd: YAG Laser Therapy Systems Model:HM-YL900 cleared under K202758.