November 30, 2023

Hebei Zhemai Technology Co., Ltd
Ray Way
Official Correspondent
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Rd, Yanjiao Development Zone, Sanhe
Langfang, Hebei 065201
China

Re: K232716
Trade/Device Name: Q-Switched Nd:Yag laser
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 4, 2023
Received: September 5, 2023

Dear Ray Way:

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.

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
2023.11.30 16:03:30 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical & 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)*
K232716

Device Name
Q-Switched Nd:Yag laser

Indications for Use *(Describe)*
The Q-Switched Nd:Yag laser 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.

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The assigned 510(k) Number: K232716

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 Title 21, CFR Section 807.92.

1. Date of Preparation:2023/11/30

2. Sponsor Identification

Hebei Zhemai Technology 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

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. Indication For Use Statement:
The Q-Switched Nd:Yag laser 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.

6. Device Description

The Q-switched laser therapy device is laser system which delivers laser at a wavelength 1064nm or 532nm and the pulse mode is single pulse.
Model: FQ-L08
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.

Table 1 Main Components introduction

No.	Component name	Function
1	Main unit	Main Interface
2	Smart Optics 7 Arms	Articulated arm for holding of Treatment Probe
3	Treatment head	Laser Deliver
4	Foot switch	Control pulse light output
5	Patient goggles	Eye protection
6	Doctor goggles	Eye protection
7	Treatment head bracket	Support and fix the treatment head
8	Key	Start device
9	Power cord	Supply power
10	Damping	It has a shock absorption effect

7. Identification of Predicate Device(s)

510(k) Number: K161926
Product Name: ND YAG Q-switch Laser Therapy Machine
Manufacturer: Beijing ADSS Development Co., Ltd

8. 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:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EC 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 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 2014 Safety of laser products - Part 1: Equipment classification, and requirements
- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- Software Validation & Verification Test

Table 2 General Comparison

ITEM	**Proposed Device**	**Predicate Device 1** K161926	Remark
Product Code	GEX	GEX	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Class	2	2	SE

Intended Use	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.	The ND YAG Q-switch Laser Therapy Machine 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.	SE

Table 3 Performance Comparison

ITEM	**Proposed Device**	**Predicate Device 1** K161926	Remark
Laser Medium	Nd:YAG	Nd:YAG	SE
Wavelength	1064nm 532nm	1064 nm 532 nm	SE
Output energy	10-1000mJ for 1064nm 50-500mJ for 532nm	100-1000mJ for 1064nm 50-500mJ for 532nm	SE
Max. Energy Density	31.8J/cm^2 for 1064nm 15.9 J/cm^2 for 532nm	31.8J/cm^2 for 1064nm 15.9 J/cm^2 for 532nm	SE
Spot Size	2-10mm	2-10mm	SE
Pulse Width	6ns	5ns-8ns	Analysis 1
Repetition Rate	1-10Hz	1-10 Hz	SE
Disinfection	Arms without focusing lenses and probes can be disinfected with a 75% medical grade alcohol wipe.	Disinfect the handpiece before and after every treatment by 75% medicinal alcohol	SE
Laser Class	Class 4	Class 4	SE
Cooling method for treated skin area	Closed water circulation	N.A.	SE

Aiming Beam	<6mW, semiconductor aiming light	Red Laser, <6mW	SE

Table 4 Safety Comparison

Item	**Proposed Device**	**Predicate Device 1** K161926	**Remark**
Patient Contact Materials and Biocompatibility			
Patient Contact Materials	Treatment Probe	Treatment Probe (Stainless Steel)	SE
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SE
Sensitization	No evidence of sensitization	No evidence of sensitization	
Irritation	No evidence of irritation	No evidence of irritation	
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 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	Comply with IEC 60601-2-22, IEC 60825	SE

Analysis 1:

The proposed device has different Pulse Width from the predicate device.

Pulse Width of proposed device is within the predicate device. And the proposed device has passed the IEC 60601-1 test, IEC 60601-1-2 test, IEC 60601-2-22 test, IEC 60825-1 test, the safety and performance of the product can be ensured.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, ND YAG Q-switch Laser Therapy Machine cleared under K161926.