April 1, 2025

Gigaalaser Company Ltd.
Xinxing Nie
Regulations Control Manager
B15-8F, Wuhan Hi-Tech Medical device park, #818 Gaoxin Road
Wuhan, Hubei 430206
China

Re: K250018
Trade/Device Name: Medical Diode Laser Systems (THEIA808)
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: January 3, 2025
Received: January 3, 2025

Dear Xinxing Nie:

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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2025.04.01 09:30:29 -04'00'

for 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250018

Device Name

Medical Diode Laser Systems (THEIA808)

Indications for Use *(Describe)*

The THEIA808 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.

510k Summary

K250018

0. Date of Preparation

25/03/2025

1. Submitter's Identifications

Submitter's Name: Gigaalaser Company Ltd.

Address: B15-8F, Wuhan Hi-Tech Medical device park, #818 Gaoxin Road, Wuhan 430206, China

Contact Person: Nie Xinxing

Contact Title: Regulations Control Manager

Contact Email Address: fdagigaalaser@sohu.com

Telephone: +86-18086025718

2. Correspondent’s Identifications

Correspondent’s Name: Gigaalaser Company Ltd.

Address: B15-8F, Wuhan Hi-Tech Medical device park, #818 Gaoxin Road, Wuhan 430206, China

Contact Person: Nie Xinxing

Contact Title: Regulations Control Manager

Contact E-mail Address: fdagigaalaser@sohu.com

Telephone: +86-18086025718

3. Name of the Device

Classification Name: Powered Laser Surgical Instrument

Trade Name: Medical Diode Laser Systems

Model: THEIA808

Classification Panel: General & Plastic Surgery

Product Code: GEX

Regulation Number: 21 CFR 878.4810

Device Classification: Class II

4. The Predicate Devices

Primary Predicate device: K162659 Diode Laser Hair Removal System

5. Device Description

The Diode laser is a kind of laser with semiconductor as working material. It consists of working material, cavity resonator and power source.

The diode laser for this unit is GaAlAs diode bar, and the wavelength is 808nm. It features impact structure, high efficiency and long lifetime. Generally the beam shall be emitted as the big beam divergence of the laser from the diode. With the unique fiber-coupling technology, the laser beam can be coupled efficiently into the handpiece.

When the THEIA808 works, the thermoelectric cooler cools the light outlet, and the main device measures the working temperature of the light outlet through the NTC temperature measuring resistor.

When the temperature reaches the minimum temperature, the TEC is controlled to stop working. The heat generated by thermoelectric cooler is conducted away by the water flow in

the cooling module.

The energy of the laser is preferentially absorbed by the melanin in the hair, so that the hair follicle produces high heat. Thereby destroying the structure of the hair follicle, making the hair lose the ability to regenerate, and achieving the purpose of hair removal. The light outlet (treatment head) adopts a uniquely designed dynamic cooling device.

During the hair removal process, it can ensure that the epidermis will not be burned, so that the laser heat is limited to damage the hair follicles, while allowing the heat to diffuse from the epidermis, so that the epidermis can be anesthetized in a short time. The skin will not reach the damage threshold and can be protected from heat damage, thus ensuring a painless, fast and permanent hair removal effect.

6. Indication for use:

The THEIA808 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.

7. Substantially Equivalent (SE) Comparison

Table 1

	Proposed device	Primary predicate device	Comparison
510k Number	K250018	K162659	------
Product Code	GEX	GEX	SE
Proprietary Name	Medical Diode Laser Systems	Diode Laser Hair Removal System	------
Model	THEIA808	HM-DL100	------
Manufacturer	Gigaalaser Company Ltd.	Shandong Huamei Technology Co., Ltd.	------

Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Class	Class II	Class II	SE
Indications for use	The THEIA808 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.	The Diode Laser Hair Removal System 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.	SE
Configuration	Main Unit	Main Unit	SE
	Handpiece	Handpiece	SE
	Foot Control	Foot Control	SE
Principle of Operation	Diode Laser	Diode Laser	SE
Laser Type	Diode Laser	Diode Laser	SE
Laser Classification	Class IV	Class IV	SE
Laser Wavelength	808 nm	808 nm	SE
Spot Size	1.44 cm^2	1.44 cm^2	SE
Fluence	5 J/cm^2 to 120J/cm^2	1-120J/ cm2	SE
Irradiance	0.7-347.8 W/cm^2	0.7-347.8 W/cm^2	SE
Frequency	Adjustable from 1 Hz to 10 Hz	0.5-15Hz	SE
Pulse Duration	22-570ms	5-400ms	Different The Pulse Duration of the proposed device is different from that of the predicate device K162659, and the

			pulse width of the device does not affect safety and effectiveness.
Power Supply	110-240 V AC, 50-60 Hz	AC 110V/60Hz	SE
Dimension	510(W)*445(L)*270(H)mm	450mm× 550mm×380mm	Different
Weight	30 kg (transport status, without water) 32 kg (full of water)	52kg	Different
Software	Yes	Yes	SE
Patient Contact Materials	Aluminum alloy and sapphire in handpiece	Sapphire in handpiece	SE
Cooling methods	Water cooling	Water cooling	SE
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SE
Sensitization	No evidence of sensitization	No evidence of sensitization	SE
Irritation	No evidence of irritation	No evidence of irritation	SE
Electromagnetic compatibility and electrical safefy compliance	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-2-22	SE
Discussion for Substantially Equivalent (SE)	The proposed device Medical Diode Laser Systems products has the same purpose as the predicate device: product code, Regulation No., Class, indications for use, Configuration, Principle of Operation, Laser Type, Laser Classification, Laser wavelength, Spot Size, Fluence, Irradiance, Power Supply, Software, Patient Contact Materials, Cooling methods, Cytotoxicity, Sensitization, Irritation and Electromagnetic compatibility and electrical safefy compliance. The difference only exists in such contents: Pulse Duration, Dimension and Weight. These items can be controlled within the scope of application. These small differences between the proposed devices and predicate devices do not cause new safety and effectiveness problems. According to the non clinical test results, the proposed device is as safe, effective and has good performance as the predicate device. So, the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.		

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:

IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

EN 60601-1-2:2015 / IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances- Requirements and tests.

EN 60601-2-22:2020 / 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.

EN 60825-1:2014 / IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements.

ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for 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.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.