



November 28, 2025

Baoding Te'anzhou Electronic Technology Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, Hebei 200120
China

Re: K252658

Trade/Device Name: Medical Diode Laser Systems (TR-B)

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 22, 2025

Received: August 22, 2025

Dear Boyle 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,

YAN FU-S

Digitally signed by YAN

FU-S

Date: 2025.11.28

13:57:09 -05'00'

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

Indications for Use

510(k) Number (if known)

K252658

Device Name

Medical Diode Laser Systems (TR-B)

Indications for Use (Describe)

The Medical Diode Laser Systems are intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is further indicated for laser assisted lipolysis. The device's 1470nm laser is intended for: Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue-Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux.

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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510(k) Summary

K252658

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

1.0 Submitter's information

Name: Baoding Te'anzhou Electronic Technology Co., Ltd.

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Address: Room 1702, 17th Floor, Zhibo Technology Comprehensive Research And Development Building, No.89, Hengbin Road, Baoding, Hebei, China.

Phone Number: +86-15631235764

Contact: Ms.Wenjia Shang

Email: Ivan@tazlaser.com

Date of Preparation: Nov.14, 2025

Prior submissions

This is the first submission, there is no prior submission.

Designated Submission Correspondent

Mr. Boyle Wang

Shanghai Truthful Information Technology Co., Ltd.

Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China

Tel: +86-21-50313932

2.0 Device information

Trade name: Medical Diode Laser Systems

Common name: Powered Laser Surgical Instrument

Regulation name: Laser surgical instrument for use in general and plastic surgery
and in dermatology

Model(s): TR-B.

3.0 Classification

Production code: GEX

Regulation number: 21 CFR 878.4810

Classification: Class II

Panel: General & Plastic Surgery

4.0 Predicate device information

Predicate device

510(k) Number: K212734
Product Name: Diode laser therapy device
Manufacturer: Triangel Rsd Limited

Reference device 1:

510(k) Number: K240179
Product Name: Medical Diode Laser (Model: L2)
Manufacturer: Wuhan Pioon Technology Co., Ltd.

Reference device 2:

510(k) Number: K082721
Product Name: LaserPro 810, LaserPro 980
Manufacturer: PhotoMedex, Inc.

5.0 Indication for Use Statement

The Medical Diode Laser Systems are intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is further indicated for laser assisted lipolysis. The device's 1470nm laser is intended for: Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue-Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux.

6.0 Device description

The Medical Diode Laser Systems generate a 980nm wavelength laser to act on a target tissue to achieve resection, hemostasis, ablation, and coagulation of the target tissue.

The Medical Diode Laser Systems generate a 1470 nm wavelength laser that acts on the water molecules of the target tissue to achieve the function of treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

The Medical Laser Family has following characteristics:

- Dual wavelengths
- Temperature monitoring system

Table 1 - Product Technical Specification

Laser type	GaAlAs diode laser
Device model	TR-B
Wavelength	980nm±20nm, 1470nm±20nm

Laser output power	980±20nm cw 20W 1470nm±20nm cw 15W
Security level	Class I type B
Laser output mode	Continuous, Pulse, Single.
Pulse width	0.1s-10s (stepping 0.1s)
Cooling	Air Cooling
Size	310(L)*290(W)*205(H) mm
Net weight	7.45KG
Fuse	F15AL250V
Aiming beam	Diode laser of 650nm, power Max. 10mW, adjustable brightness.
Beam divergence	314 mrad to 443 mrad
Application systems	Fiber core diameter: 400µm 600µm NA≥0.22 With SMA905 connector Before use must be sterilized
Transmission system	Contact: fibers of 400µm or 600µm with SMA905 connector; Non-contact: fibers and tips
Operation interface	Color LCD touch screen
Power supply	100-220VAC, 50/60Hz, 2.6-1.0A
Waterproof level	IPX1
Footswitch Waterproof level	IPX8
Transportation & Storage environmental conditions	Temperature:-20°C~70°C, Relative humidity: 10%~90%, Atmospheric pressure: 80KPa~106KPa Without sensible vibration and shock
Application environmental conditions	Temperature:10°C~40°C, Relative humidity: 10%~90%, Atmospheric pressure: 80KPa~106KPa

7.0 Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the subject devices met all design specifications as were 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
- 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 Edition 4.0 2019-11, Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825 Edition 2.0 2007-03, Part 1: Equipment classification and

requirements

- IEC 60601-1-6 Edition 3.2 2020-07, Medical electrical equipment - Part 4-2: Guidance and interpretation - Guidance for the application of ISO 14971
- IEC 60601-4-2 Edition 1.0 2016-05, Guidance and interpretation- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.
- Software verification and validation testing were conducted and documentation was provided as recommended by FDA' s Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Function". The recommended Documentation Level for software of this device was considered as a "Basic Documentation Level" and the documentation was provided accordingly.
- Usability testing conducted.
- Performance testing conducted to validate the output specifications of the device.

8.0 Clinical Test Conclusion

No clinical study implemented for the Diode laser therapy device.

9.0 Technological Characteristic Comparison Table

Table 2 - General Comparison

Item	Proposed device	Predicated device	Reference device 1	Reference device 2	Remark
Product Code	GEX	GEX	GEX	GEX	Identical
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical
Class	II	II	II	II	Identical
Product name	Medical Diode Laser Systems	Diode laser therapy device	Medical Diode Laser	LaserPro 810, LaserPro 980	-
510(k) No.	K252658	K212734	K240179	K082721	-
Models	TR-B	ST-AR	L2	-	-
Indications for Use	The Medical Diode Laser Systems are intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures,	The Diode laser therapy device is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The device's 980nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures,	The Medical Diode Laser (Model: L2) is indicated for: -Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue-Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux	The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the hemostasis, ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic(dermatology and plastic surgery),	Same

	gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is further indicated for laser assisted lipolysis. The device's 1470nm laser is intended for: Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue-Endovascular coagulation and endovenous occlusion of the greatest saphenous vein in patients with superficial vein reflux.	gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is further indicated for laser assisted lipolysis. The device's 1470nm laser is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures, indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.		gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, arthroscopy, podiatry, pulmonology, and thoracic surgery; and Laser Assisted Lipolysis (980 nm only).	
Patient Population	Adult	Adult	Adult	Adult	Same

Table 3 - Performance Comparison

Item	Proposed Device	Predicate Device	Reference device 1	Reference device 2	Remark
	Medical Diode Laser Systems	Diode laser therapy device	Medical Diode Laser	LaserPro 810, LaserPro 980	
	N/A	K212734	K240179	K082721	

Wavelength	980nm±20nm, 1470nm±20nm	980nm±5nm, 1470nm±10nm	1470 nm	980 nm	* Gap 1
Output Power max.	20W/980nm±20nm, 15W/1470nm±20nm	16W/980nm±20%, 4.5W/1470nm±20%	Up to 20W	1-25W/980nm	* Gap 2
Aiming beam	Diode laser of 650nm, power Max. 10mW, adjustable brightness.	650 nm, red 0.5 mW, user controlled intensity	Undisclosed data	635-650nm, adjustable intensity	* Gap 3
Treatment mode	Continuous or Pulsed	Continuous or Pulsed	Continuous or Pulsed	Continuous or Pulsed	Same
Power supply	100-220VAC, 50/60Hz	AC110V±11V, 60HZ	110/220 V	100-240 VAC, 540VA max, 50/60Hz	* Gap 4
Interval	980nm 1% ~ 100%, 1470nm 2% ~100%, continuously adjustable energy	980nm 1% ~ 100%, 1470nm 2% ~100%, continuously adjustable energy	1470nm 2% ~100%, continuously adjustable energy	980nm 1% ~ 100%, continuously adjustable energy	Same
Cooling system	Air cooled	Air cooled	Air cooled	Air cooled	Same
Pulse duration range	0.1 - 10 s	0.05 ms - 1 s	10 ms - 10 s	0.05 s - 10 s	* Gap 5

* Gap analysis:

Gap 1: Both of the proposed device and predicate device have 980nm and 1470nm wavelength. The deviations of wavelength are similar, which does not create additional risk to the product use.

Gap 2: The 980nm max power of the proposed device is close to the predicate device, which does not create additional risk to the product use.

For 1470nm max power of the proposed device is the same with reference devices, which does not create additional risks.

Gap 3: The aiming beam of the devices are close, which difference does not create additional risks to the product clinical use.

Gap 4: The power supply range of the proposed device is included in the predicate device and reference devices.

Gap 5: The pulse duration range for subject device is 0.1 - 10 seconds, while the range for predicate device K212734 is 0.05 milliseconds - 1 second.

For the difference of pulse duration range, we' ve decided to introduce reference devices.

We have add the new reference devices K240179 and K082721.

The pulse duration range for reference device K240179 is 10 ms - 10 s @1470nm.

The pulse duration range for reference device K082721 is 0.05 s - 10 s @980nm.

Both of the reference devices can comprehensively cover the pulse duration range for subject device.

Therefore, this difference will not affect the safety and effectiveness.

Table 4 - Safety Comparison

Item	Proposed Device	Predicate Device	Reference device 1	Reference device 2	Remark
	Medical Diode Laser Systems	Diode laser therapy device	Medical Diode Laser	LaserPro 810, LaserPro 980	
	Pending	K212734	K240179	K082721	
Electric safety	Comply with IEC 60601-1:2005+A1:2012+A2 :2020, IEC 60825-1:2014, IEC 60601-2-22:2019	Comply with IEC 60601-1:2005+A1:2012, IEC 60825-1:2014, IEC 60601-2-22:2007+A1:2012	Comply with IEC 60601-1, IEC 60825-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60825-1, IEC 60601-2-22	Same
EMC	Comply with IEC 60601-1-2:2014+A1:2021	Comply with IEC 60601-1-2:2014	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Medical Diode Laser Systems is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K212734.