November 7, 2025

Baoding Te'anzhou Electronic Technology Co., Ltd.
% Long Yang
General Manager
Shenzhen Hlongmed Biotech Co.,Ltd.
16th floor,Tianming Technology Building
No.8 Wushitou Road, North High-tech District, Nanshan
Shenzhen, 518000
China

Re: K252564
Trade/Device Name: Medical Diode Laser Systems (VeinCure)
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 14, 2025
Received: August 14, 2025

Dear Long Yang:

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: 2025.11.07 22:16:50 -05'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252564

Device Name

Medical Diode Laser Systems (VeinCure)

Indications for Use *(Describe)*

The "VeinCure" is indicated for use in the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

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

(as required by 807.92(c))

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR & 807.92

The assigned 510(K) number is: K252564

Date of Summary: Oct 10, 2025

1. Submitter information

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

Address: Room 1702, 17th Floor, Zhibo Technology Comprehensive R&d Building, No. 89, Hengbin Road, Baoding, Hebei, China

Contact Person and Title：Ji chuan Cao (General manager)

Tel: 0086-15631235764

Email: lvan@tazlaser.com

2. Contact person

2.1 Primary Contact Person

Long Yang (General manager)

Shenzhen Hlongmed Biotech Co.,Ltd.

16th floor,Tianming Technology Building, No.8 Wushitou Road, North High-tech District, Nanshan, Shenzhen,PRC

Tel: 0086-755-86664986

Fax: 0086-755-86664933

E-mail: yanglong@hlongmed.com

2.2 Secondary Contact Person

Ji chuan Cao (General manager)

Baoding Te'anzhou Electronic Technology Co., Ltd.

Room 1702, 17th Floor, Zhibo Technology Comprehensive R&d Building, No. 89, Hengbin Road, Baoding, Hebei, China

Tel: 0086-15631235764

E-mail: lvan@tazlaser.com

3. Device information

Type of 510(k) submission	Traditional
Device name	Medical Diode Laser Systems
Model	VeinCure
Common name	Medical Diode Laser Systems
Review Panel	General & Plastic Surgery
Product Code	GEX
Regulation Number	21 CFR 878.4810
Device Class	II

4. Predicate device information

510(k) number	K211977
Device name	Medical Diode Laser Systems
Sponsor	Wuhan Dimed Laser Technology Co., Ltd.
Product code	GEX

5. Device Description

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 (Gallium-aluminum-arsenic) diode bar, and the wavelength is 1470nm. It features impact structure, high efficiency and long lifetime. Generally the beam shall be shamed as the big beam divergence of the laser from the diode. When the

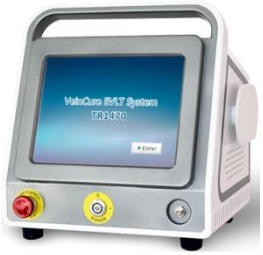
coaxiality of laser and fiber meet the requirements, the laser beam can be coupled efficiently into the fiber.

6. Intended Use/Indications for Use

The "VeinCure" is indicated for use in the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

7. Technological characteristics and Substantial Equivalence

The following is a comparison between the Medical Diode Laser Systems (model:VeinCure) (Subject Device) and legally marketed device. The result shows the conformance of Subject Device to the Predicate Devices.

No.	Item of Comparison	Predicate device	Subject device	Discussion
1	510K Number	K211977	/	NA
2	Proprietary Name	Medical Diode Laser Systems	Medical Diode Laser Systems	NA
3	Model	CHERYLAS-15N; CHERYLAS-20N	VeinCure	NA
4	Manufacturer	Wuhan Dimed Laser Technology Co., Ltd.	Baoding Te'anzhou Electronic Technology Co., Ltd.	NA
5	Product picture			NA

6	Classification name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	similar
7	Product Code	GEX	GEX	similar
8	Regulation Number	21 CFR 878.4810	21 CFR 878.4810	similar
9	Intended use/ Indication for use	The "CHERYLAS-15N and CHERYLAS-20N" are indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	The "VeinCure" is indicated for use in the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	similar
10	Laser Type	diode laser	diode laser	similar
11	Components	Laser system, Color touch screen, Foot switch	Laser system, Color touch screen, Foot switch	similar
12	Wavelength	1470nm	1470nm	similar
13	Output power	CHERYLAS-15N: 0.1W-15W; CHERYLAS-20N: 0.1W-20W;	VeinCure: 0.1W-15W	similar
14	Operation mode	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse	similar
15	Pulse width	10ms- 3s	**10ms-2.50s**	similar
16	Pulse repetition rate	0.2Hz-50Hz	0.2Hz-50Hz	similar
17	Application / Light delivery	It is recommended to use the disposable sterile fiber (K124003,	It is recommended to use the disposable sterile fiber (K124003,	similar

	system	MED-Fibers, Inc.) registered in U.S.A. The parameters must meet the following requirements: ●bare fiber, long as 3m ●Fiber core diameter: 600μm ●NA ≥0.22 ●With SMA905 connector ●Single used	MED-Fibers, Inc.) registered in U.S.A. The parameters must meet the following requirements: ●bare fiber, long as 3m ●Fiber core diameter: 600μm ●NA ≥0.22 ●With SMA905 connector ●Single used	
18	Aiming Beam	Diode laser of 650nm, power <3mW, adjustable brightness.	Diode laser of 650nm, power <3mW, adjustable brightness.	similar
19	Laser Class	4	4	similar
20	Operation interface	Color LCD touch screen	Color LCD touch screen	similar
21	Power Supply	100-240VAC, 50/60Hz, 1.4A	100-240VAC,50/60Hz,2.6-1.0A	Different 1
22	Safety classification	ClassI Type B	ClassI Type B	similar
23	Dimensions	380(W)*430(L)*220(H) mm	320(W)*280(L)*320(H) mm	Different 2
24	Weight	11kg	7.1 Kg	Different 3
25	Waterproof level	IPX1	IPX1	similar
26	Footswitch Waterproof level	IPX8	IPX8	similar
27	Standard	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	similar

28	Non-sterile	Yes	Yes	similar
29	Microprocessor Control	Yes	Yes	similar

The subject device has same intended use, similar product design, same performance effectiveness, and performance safety as the predicate device.

The differences between the subject device and predicate device are minor and both products meet the standard IEC60601-1, IEC60601-1-2, IEC60601-2-22 and IEC60825-1. The differences between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

Argument for Substantial Equivalence to Predicate Devices

As seen in the comparison tables, the subject and predicate device have the same intended use and similar technological characteristics. The main technological differences between the subject and predicate device are minor differences, and do not raise different questions of safety or effectiveness. Information contained in this submission demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness.

Thus, the subject device is substantially equivalent to the predicate device.

8. Performance Data

Clinical data

Not applicable.

Non-clinical data:

The Medical Diode Laser Systems (Model: VeinCure) conforms to applicable standards included IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;

IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests; IEC60601-2-22:2019 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment and IEC60825-1:2014 Safety of laser products - Part 1: Equipment classification, and requirements.

9. Conclusion

The non-clinical data support the safety of the device and the software verification and validation demonstrate that the Medical Diode Laser Systems (model:VeinCure) should perform as intended in the specified use conditions, and all the data demonstrate that the subject device performs comparably to the predicate device that is currently marketed for the same intended use. In other words, the subject device Medical Diode Laser Systems (model:VeinCure) is substantially equivalent to the predicate device K211977.