September 25, 2025

Wuhan Dimed Laser Technology Co., Ltd.
% Yuling Chen
RA manager
Linnwell International Certification Consulting Co., Ltd.
Room 310, Building 2, No. 110 Xinjunhuan Road
Minhang District
Shanghai, 201112
China

Re: K252063
Trade/Device Name: Medical Diode Laser Systems (BERYLAS-12N); Medical Diode Laser Systems (BERYLAS-15N); Medical Diode Laser Systems (HARLAS-45JN); Medical Diode Laser Systems (HARLAS-46JN)
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: June 23, 2025
Received: July 1, 2025

Dear Yuling Chen:

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: 2025.09.25 18:36:07 -04'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252063

Please provide the device trade name(s).

Medical Diode Laser Systems (BERYLAS-12N);
Medical Diode Laser Systems (BERYLAS-15N);
Medical Diode Laser Systems (HARLAS-45JN);
Medical Diode Laser Systems (HARLAS-46JN)

Please provide your Indications for Use below.

BERYLAS-12N/BERYLAS-15N
The BERYLAS-12N and the BERYLAS-15N are indicated for the treatment of reflux of the saphenous veins associated with varicose verins and varicosities.

HARLAS-45JN/HARLAS-46JN
1470nm:Indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.
980nm:Indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (UJrology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery (PLDD), Gastroenterology, Head/neck/ENT and Radiology Endovascular coagulation, Oral Surgery and Dental procedures, laser assisted lipolysis.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
K252063

This summary of 510(k) is submitted in accordance with the requirements of 21 CFR 807.92.

1.Submitter Information

Manufacturer	Manufacturer: Wuhan Dimed Laser Technology Co., Ltd. Address: Room 311, 313, 315, Hubei Guozhi Patent Venture Incubator Building, 327-1 Minzu Avenue, Wuhan East Lake High-tech Development Zone, Wuhan, Hubei, 430223, China. Postcode: 430223
Contact Person	Yuling Chen Linnwell International Certification Consulting Co., Ltd. Email: Yuling.chen@linnwell.com Phone: +86 15021397762
Date Prepared	September 17, 2025

2.Device Information

Device Generic Name: Medical Diode Laser Systems

Device Trade Name: NA

Model of System: BERYLAS-12N, BERYLAS-15N, HARLAS-46JN, HARLAS-45JN

Regulation number: 21 CFR 878.4810

Regulation Name: Powered laser surgical instrument

Regulation Class: Class II

Product Code: GEX

3.Predicate Device

	For BERYLAS-15N/BERYLAS-12N	For HARLAS-46JN/HARLAS-45JN
Product name	Medical Diode Laser Systems	Medical Diode Laser Systems
Trade name	CHERYLAS-15N CHERYLAS-20N	CHERYLAS-15N CHERYLAS-20N VELASII-30B
510(k) Number	1470nm: K211977	1470nm: K211977

		980nm: K151890
Regulation number	21 CFR 878.4810	
Regulation Name	Medical Diode Laser Systems	
Regulation Class	II	
Product Code	GEX	
Manufacture	Wuhan Dimed Laser Technology Co., Ltd.	1470nm: Wuhan Dimed Laser Technology Co., Ltd. 980nm: Wuhan Gigaa Optronics Technology Co., Ltd.

4.Indications for Use

The BERYLAS-15N and the BERYLAS-12N are indicated for the treatment of reflux of the saphenous veins associated with varicose verins and varicosities.

The HARLAS-46JN/HARLAS-45JN
1470nm: Indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.
980nm: Indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (UJrology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery (PLDD), Gastroenterology, Head/neck/ENT and Radiology Endovascular coagulation, Oral Surgery and Dental procedures, laser assisted lipolysis.

5.Device Description

Medical Diode Laser Systems is Class 4 Laser Product according to 21CFR 1040.10 and IEC 60825-1:2014, which utilizes a solid state diode as a semiconductor source for invisible infrared

radiation wavelength. The working beam of BERYLAS-15N and BERYLAS-12N is 1470nm, the working beam of HARLAS-46JN and HARLAS-45JN are 1470nm and 980nm. The max. Laser output power of BERYLAS-15N is 15W, the max. Laser output of BERYLAS-12N is 12W, the max. Laser output power of HARLAS-46JN is 16W for 1470nm and 30W for 980nm and the max. Laser output power of HARLAS-45JN is 15W for 1470nm and 30W for 980nm. The energy is delivered to the treatment site via flexible fiber connected with the Laser Aperture. The treatment parameters, such as, Power, Laser Emission Mode, Interval and Duration (for Pulse modes), and treatment time, can be set via the embedded software.

Although Fiber is not a component of BERYLAS-12N, BERYLAS-15N, HARLAS-45JN and HARLAS-46JN, a compatible fiber is required to delivery laser energy to the patient. MED-Fibers Surgical Laser Fibers (core diameter size 600μm) manufactured by MED Fibers, Inc. are recommend, their 510(K) number is K124003.

6.Comparison to predicate device

Table 1. BERYLAS-15N/BERYLAS-12N vs. CHERYLAS-15N/CHERYLAS-12N

	Proposed Device	**Predicate device**	**Discussion**
510k Number	K252063	K211977	/
Product Code	GEX	GEX	/
Model	BERYLAS-12N, BERYLAS-15N	CHERYLAS-15N; CHERYLAS-20N	/
Manufacturer	Wuhan Dimed Laser Technology Co., Ltd.	Wuhan Dimed Laser Technology Co., Ltd.	/
Product picture			/
Indications for use	Indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	Indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	Same
Wavelength	1470nm	1470nm	Same

	Proposed Device	Predicate device	Discussion
Operation mode	CW, Repeat Pulse	CW, single pulse, repeat pulse	SE
Pulse width	10ms-3s	10ms-3s	Same
Aiming Beam	Diode laser of 650nm, power <5mW, adjustable brightness	Diode laser of 650nm, power <3mW, adjustable brightness.	SE
Laser Class	4	4	Same

Table 2 HARLAS-45JN/46JN vs. CHERYLAS-15N/20N and VELASII-30B

	Proposed Device	Predicate device 1	Predicate device	Discussion
510k Number	K252063	K211977	K151890	/
Product Code	GEX	GEX	GEX	/
Model	HARLAS-46JN; HARLAS-45JN	CHERYLAS-15N; CHERYLAS-20N	VELASII-30B	/
Manufacturer	Wuhan Dimed Laser Technology Co., Ltd.	Wuhan Dimed Laser Technology Co., Ltd.	Wuhan Gigaa Optronics Technology Co., Ltd.	/
Product picture				/
Indications for use	1470nm: Indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities. 980nm: Indicated for use in surgical applications requiring the	Indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	The “VELASII-30B” are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (UJrology),	Same The indications for use of 1470nm is the same with Predicate device 1. The indications for use of 980nm is the same with Predicate device 2.

	Proposed Device	Predicate device 1	Predicate device	Discussion
	vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (UJrology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery (PLDD), Gastroenterology, Head/neck/ENT and Radiology Endovascular coagulation, Oral Surgery and Dental procedures, laser assisted lipolysis.		Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery (PLDD), Gastroenterology, Head/neck/ENT and Radiology Endovascular coagulation, Oral Surgery and Dental procedures, laser assisted lipolysis.	

	Proposed Device	Predicate device 1	Predicate device	Discussion
Wavelength	980nm, 1470nm	1470nm	980nm	Same Proposed device has two wavelength, one of them is 1470nm, which is the same with Predicate device 1, another wavelength is 980nm, which is the same with Predicate device 2.
Output power	HARLAS-46JN: 980nm:0.1W-30W; 1470nm:0.1W-16W HARLAS-45JN: 980nm:0.1W-30W; 1470nm:0.1W-15W	CHERYLAS-15N: 0.1W-15W CHERYLAS-20N: 0.1W-20W	1-30W	SE.
Operation mode	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse	Same
Pulse width	10ms-3s	10ms-3s	10ms-2.5s	SE
Aiming Beam	Diode laser of 635nm, power <5mW, adjustable brightness	Diode laser of 650nm, power <3mW, adjustable brightness.	Diode laser of 635/532nm, power max.<5mW, adjustable brightness.	SE
Laser Class	4	4	4	Same

7. Non-Clinical Test

This device has been tested and evaluated under the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)];
- IEC 60601-1-2:2014 + A1:2020: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic disturbances-Requirements and tests.

- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISO 14971:2019 Medical devices - Application of risk management to medical devices.
- IEC 62304:2006+AMD1:2015 medical device software - software life cycle processes.
- 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

8. Clinical Studies

Not applicable. The subject devices of this submission, does not require clinical studies to support substantial equivalence.

9.Summary

Based on the performance data as documented in the study, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

10. Conclusion

The performance testing support that the subject device is as safe and effective as the predicate Devices K211977 and K151890. Therefore, the subject device is substantially equivalent to the predicate device.