October 26, 2021

Wuhan Dimed Laser Technology Co., Ltd.
Long Yang, COO
Shenzhen Hlongmed Biotech Co., Ltd.
1201, Haosheng Business Center, 4096 Dongbin Road, Nanshan
Shenzhen, Guangdong 518054
China

Re: K211977
Trade/Device Name: Medical Diode Laser Systems
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: July 30, 2021
Received: August 6, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Purva Pandya
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211977

Device Name
Medical Diode Laser Systems

Indications for Use *(Describe)*
The "CHERYLAS-15N and CHERYLAS-20N" are indicated for 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.

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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 SMDA 1990 and 21 CFR & 807.92.

The assigned 510(K) number is: K211977

Date of Summary: 2021.10.26

1. Submitter information

Submitter Name: Wuhan Dimed Laser Technology Co., Ltd.

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2. Contact person

2.1 Primary Contact Person

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2.2 Secondary Contact Person

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Tel: 0086-15827482600

3. Device information

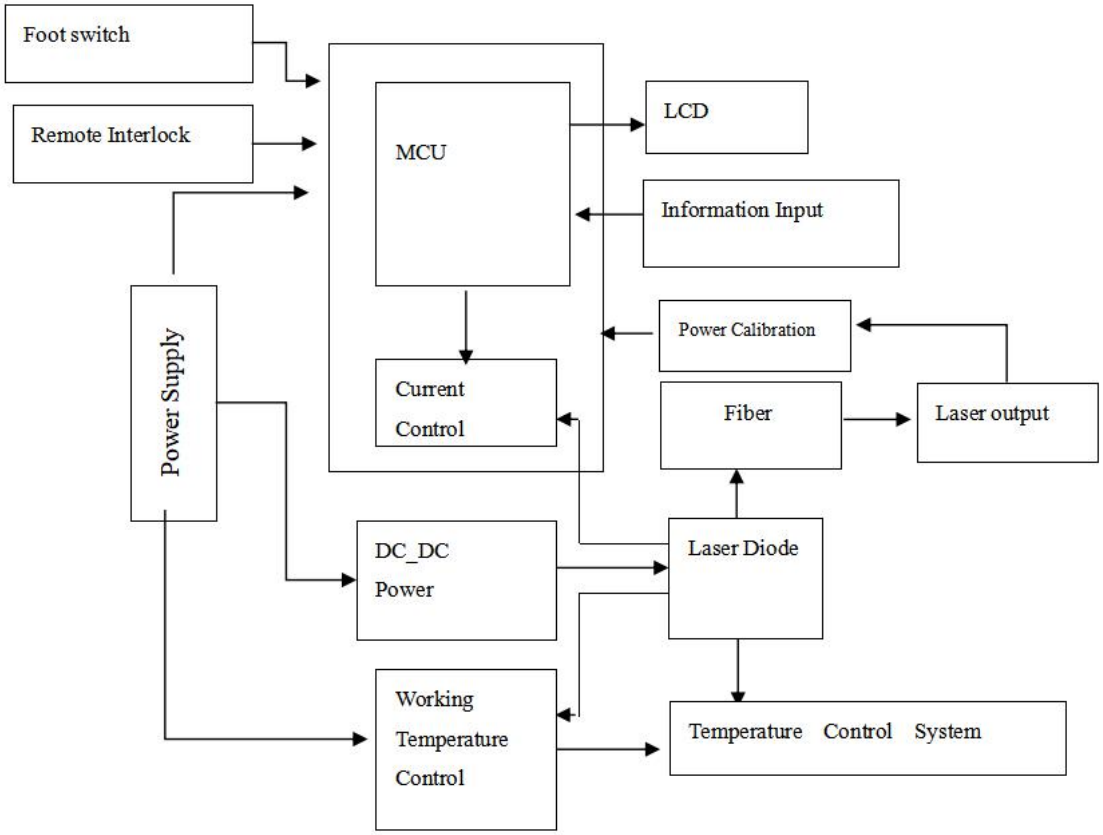
Type of 510(k) submission	Traditional
Device name	Medical Diode Laser Systems
Model	CHERYLAS-15N, CHERYLAS-20N
Common name	Medical Diode Laser Systems
Review Panel	General & Plastic Surgery
Product Code	GEX
Regulation Number	21 CFR 878.4810
Device Class	II

4. Predicate device information

510(k)number	K160549
Device name	Medical Diode Laser Systems
Sponsor	Wuhan Gigaa Optronics 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 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.



The block diagram shows how the diode laser system works. MCU (Micro Controller Unit) is the control center of system. MCU controls the drive board and temperature system by changing operating current. The operating power supply is the power source of the whole system, it supplies power for MCU, diode laser module by DC-DC conversion module and temp system by temp-control circuit. MCU controls the drive current of diode laser module by adjusting the DC-DC module and current-control circuit. The MCU has three external input sources: footswitch, remote interlock and information input from the touch units, it has one external output unit: display terminal. The diode laser module provides laser power output by fiber with optical fiber coupling system. The system can test and calibrate power by the calibration and feedback unit.

6. Intended use

The "CHERYLAS-15N and CHERYLAS-20N" are indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

7. Technological characteristics and Substantial Equivalence

Wuhan Dimed Laser Technology Co., Ltd. believes the CHERYLAS-15N, CHERYLAS-20N described in this submission is substantially equivalent to the predicate device as follows:

No.	Item of Comparison	Predicate device	Subject device	Discussion
1	510K Number	K160549	K211977	NA
2	Proprietary Name	Medical Diode Laser Systems	Medical Diode Laser Systems	NA
3	Model	VELAS II-15D	CHERYLAS-15N; CHERYLAS-20N	NA
4	Manufacturer	Wuhan Gigaa Optronics Technology Co., Ltd.	Wuhan Dimed Laser Technology Co., Ltd.	NA
5	Product picture			NA
6	Classification name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	Same
7	Product Code	GEX	GEX	Same
8	Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Same
9	Intended use/ Indication for	The “VELAS II-15D” is indicated for use in the	The “CHERYLAS-15N and CHERYLAS-20N”	Same

	use	treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	are indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	
10	Laser Type	diode laser	diode laser	Same
11	Components	Laser system, Color touch screen, Foot switch, Power detector	Laser system, Color touch screen, Foot switch	Different
12	Wavelength	1470nm	1470nm	Same
13	Output power	VELAS II-15D: 1-15W	CHERYLAS-15N: 0.1W-15W; CHERYLAS-20N: 0.1W-20W;	Similar
14	Operation mode	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse	Same
15	Pulse width	10ms-2.5s	10ms- 3s	Similar
16	Pulse repetition rate	0.2Hz-50Hz	0.2Hz-50Hz	Same
17	Application / Light delivery system	It is recommended to use the disposable sterile fiber (K124003, MED-Fibers, Inc.) registered in U.S.A.	It is recommended to use the disposable sterile fiber (K124003, MED-Fibers, Inc.) registered in U.S.A.	Same

		The parameters must meet the following requirements: ●bare fiber, long as 3m ●Fiber core diameter: 600μm ●NA ≥0.22 ● With SMA905 connector ●Single used	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 635/532nm, power max.<5mW, adjustable brightness.	Diode laser of 650nm, power <3mW, adjustable brightness.	Different
19	Laser Class	4	4	Same
20	Operation interface	Color LCD touch screen	Color LCD touch screen	Same
21	Power Supply	100-240VAC, 50/60Hz, 350VA	100-240VAC, 50/60Hz, 1.4A	Different
22	Safety classification	ClassI Type B	ClassI Type B	Same
23	Dimensions	400(W)*385(L)*200(H)mm	380(W)*430(L)*220(H) mm	Similar
24	Weight	12.9kg	11kg	Similar
25	Waterproof level	IPX1	IPX1	Same

26	Footswitch Waterproof level	IPX8	IPX8	Same
27	Standard	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	Same
28	Non-sterile	Yes	Yes	Same
29	Microprocessor Control	Yes	Yes	Same

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 same 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. Effectiveness and Safety Considerations

Clinical data

Not applicable.

Non-clinical data:

The Medical Diode Laser Systems (Model: CHERYLAS-15N, CHERYLAS-20N) conforms to applicable standards included below requirements.

- AAMI / ANSI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R) 2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD),
- IEC60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests,
- IEC 60601-2-22:2007+AMD1: 2012 CSV Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment and
- IEC60825-1:2007 Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

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: CHERYLAS-15N, CHERYLAS-20N) device should perform as intended in the specified use conditions, and all the data demonstrate that the subject device perform comparably to the predicate device that is currently marketed for the similar intended use. In other words, the subject

device Medical Diode Laser Systems (Model: CHERYLAS-15N, CHERYLAS-20N) is substantially equivalent to the predicate device.