August 3, 2023

Wuhan Pioon Technology Co., Ltd.
℅ Valerie Followell
Senior RA & QA Consultant
Lean RAQA
131 E Loch Lomond Dr
Oro Valley, Arizona 85737

Re: K231548
Trade/Device Name: Meical Diode Laser, Model S1Pro
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: May 30, 2023
Received: May 30, 2023

Dear Valerie Followell:

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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K231548

Device Name
Medical Diode Laser ,Model S1Pro

Indications for Use *(Describe)*

The Medical Diode Laser ,Model S1Pro is 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)*

[X] 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

In accordance with the content and format regulatory requirements of 21 CFR Part 807.92,the 510(k) Summary for the Medical Diode Laser is provided below.

The assigned 510(k) Number: **K231548**

1. Submitter

Device Submitter: Wuhan Pioon Technology Co.,Ltd.
Address:7th Floor, A21 of Sino Pharm Building, Biolake Innovation Park, No.666 Gaoxin Avenue, East Lake High-tech Development Zone,430075,Wuhan, Hubei, PEOPLE'S REPUBLIC OF CHINA
Tel: +86 27 81783687

Contact Person: Zhang Feng, Official Primary Correspondent and Management Representative
Phone: +86 18062448535
E-mail: zhangfeng@pioon.com

Official Correspondent: Valerie Followell, LeanRAQA Consulting
Phone: 847-400-6187
Email:followell@leanraqa.com

Date Prepared: July 14, 2023

2. Device

Type of 510(k) submission: Traditional
Device name: Medical Diode Laser
Model: S1Pro
Common Name: Powered Laser Surgical Instrument
Regulation: 878.4810 - Laser surgical instrument for use in general and plastic surgery and in dermatology
Medical Specialty: General & Plastic Surgery
Regulatory Class: II
Product Code: GEX

3. Predicate Device

Wuhan Dimed Laser Technology Co., Ltd. Medical Diode Laser Systems, Model: CHERYLAS-15N,CHERYLAS-20N - K211977.

4. Device Description

The Medical Diode Laser use a wavelength 1470nm Galium Aluminum Arsenide (GaAlAs) diode laser as the beam source. The laser utilizes a red (650nm) aiming beam diode to indicate the area to be irradiated by the laser

beam. The Medical Diode Laser (model: S1Pro) is a compact diode laser with a LCD touchscreen for user control. The device is composed of main unit, foot switch, power cord and protective goggles. The fiber delivery system is not include in this device. The device accepts a fiber with single core of 400μm and 600μm in diameter and with SMA905 connectors.

5. Indications for Use

The Medical Diode Laser ,Model S1Pro is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.

6. Comparison to the Predicate Device

The Medical Diode Laser Systems ,S1Pro has been compared to the Medical Diode Laser Systems ,CHERYLAS-15N and CHERYLAS-20N- K211977 as reference for substantial equivalence. A table comparing the predicate device to the subject device is shown as the following:

Item	Predicate Device	Subject Device	Comparison
510(k) Number	K211977	NA	NA
Product Code	GEX	GEX	Same
Proprietary Name	Medical Diode Laser Systems	Medical Diode Laser	NA
Model	CHERYLAS-15N; CHERYLAS-20N	S1Pro	NA
Manufacturer	Wuhan Dimed Laser Technology Co., Ltd.	Wuhan Pioon Technology Co.,Ltd.	NA
Product picture			NA

Classification name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	Same
Product Code	GEX	GEX	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Same
Indications for Use	The "CHERYLAS-15N and CHERYLAS-20N " are indicated for use in the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	The Medical Diode Laser ,Model S1Pro is indicated for use in the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	Same
Laser Type	diode laser	diode laser	Same
Components	Laser system, Color touch screen, Foot switch	Laser system, Color touch screen, Foot switch	Same
Wavelength	1470nm	1470nm	Same
Output power	CHERYLAS-15N: 0.1W-15W; CHERYLAS-20N: 0.1W-20W;	S1Pro: 0-12W	Similar
Operation mode	CW, single pulse, repeat pulse	CW, single pulse, repeat pulse	Same
Pulse width	10ms- 3s	10ms-25s	Different
Pulse repetition rate	0.2Hz-50Hz	0-50Hz	Similar
Application / Light delivery system	It is recommended to use the disposable sterile fiber (K124003, 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	It is recommended to use the disposable sterile fiber (K124003, MED-Fibers, Inc.) registered in U.S.A. The parameters must meet the following requirements: ●Fiber core diameter:400μm, 600μm ●NA ≥0.22	Similar

	● With SMA905 connector ●Single used	● With SMA905 connector ●Single used	
Aiming Beam	Diode laser of 650nm, power <3mW, adjustable brightness.	Diode laser of 650nm, power <2mW, adjustable brightness.	Similar
Laser Class	4	4	Same
Operation interface	Color LCD touch screen	Color LCD touch screen	Same
Power Supply	100-240VAC, 50/60Hz, 1.4A	100-240VAC, 50/60Hz, 24VDC，2.5A Max	Similar
Safety classification	ClassI Type B	ClassI Type B	Same
Dimensions	380(W)*430(L)*220(H) mm	210 (W)* 210 (L)* 140(H) mm	Different
Weight	11kg	≤4KG NW	Different
Waterproof level	IPX1	IPX0	Different
Footswitch Waterproof level	IPX8	IPX8	Same
Standard	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	IEC60601-1 IEC60601-1-2 IEC60601-2-22 IEC60825-1	Same
Non- sterile	Fiber is sterilized by EO.	Fiber is sterilized by EO.	Same
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.

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.

7. Performance Data

Clinical data:

Not applicable.

Non-clinical data:

Electrical Compatibility and Electrical Safety

The Medical Diode Laser and optical fibers were assessed for conformity with the relevant requirements of the following standards and found to comply:

• IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

• IEC 60601-1-2:2014+A1:2020 (Fourth Edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.

Performance Testing – Bench

Pioon has conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its accuracy specification and meet relevant consensus standards. □

• 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

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern and the documentation was provided accordingly.

8. Conclusions

The non-clinical data support the safety of the device and the software verification and validation demonstrate that the Medical Diode Laser Systems (Model: S1Pro) 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: S1Pro) is substantially equivalent to the predicate device.