March 21, 2024

Wuhan Pioon Technology Co., Ltd.
Tracy Liu
Regulatory Affairs
7th Floor, A21 of Sino Pharm Bldg, Biolake Innovation Park,
No.666 Gaoxin Avenue,East Lake High-tech Development Zone
Wuhan, hubei 430075
China

Re: K240179
Trade/Device Name: Medical Diode Laser (Model: L2)
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: January 23, 2024
Received: January 23, 2024

Dear Tracy Liu:

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.

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
2024.03.21 12:37:28 -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

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)*

K240179

Device Name

Medical Diode Laser (Model: L2)

Indications for Use *(Describe)*

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

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.

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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: **K240179**

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, China
Tel: +86 27 81783687

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

Date Prepared: January 23, 2024

Official Correspondent: Tracy Liu, Wuhan Pioon Technology Co.,Ltd.
Phone: +86 15012997429
Email: tracy@pioon.com

2. Device

Type of 510(k) submission: Traditional
Device name: Medical Diode Laser
Model: L2
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

Fotona SkyPulse Laser Platform (K193656), 1470nm Diode Laser.
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

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: L2) 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 included 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: 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

6. Comparison to the Predicate Device

The Medical Diode Laser (Model: L2) ,has been compared to the 1470 nm Diode Laser Module of Fotona SkyPulse Laser Platform(K193656) as reference for substantial equivalence. A table comparing the predicate device to the subject device is shown as the following:

Item	Subject device (this submission)	Predicated device (K193656)	Comparison Result
Product Code	GEX	GEX	Same
Regulation NO.	21 CFR 878.4810	21 CFR 878.4810	Same
Class	II	II	Same
Indications for use	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	1470 nm Diode Laser: -Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue -Endovascular coagulation and endovenous occlusion of the greatest	Same

	vein in patients with superficial vein reflux	saphenous vein in patients with superficial vein reflux	
Use of device	Rx only	Rx only	Same
Energy source	Solid state diode	Solid state diode	Same
Configuration	Main Unit	Main Unit	Same
	Foot Control	Foot Control	
Laser Wavelength	1470nm	1470nm	Same
Laser Classification	Class IV	Class IV	Same
Power range	Up to 20W	Up to 22W	Similar(Within the range of the predicate)
Pulse width	CW or 10 ms – 10 s	CW or 10 ms – 10 s	Same
Repetition rate	CW or up to 100 Hz	CW or up to 100 Hz	Same
Delivery system	Fiber delivery	Fiber delivery	Same
User interface	Touch screen control	Touch screen control	Same
Safety feature	Complied with: IEC 60601-1:2005+AMD1: 2012+AMD2:2020(IEC 60601-1:2020) IEC 60601-1-2:2014+A1:2020 IEC 60601-2-22:2019 IEC 60825-1:2014	Complied with: IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014 IEC 60601-2-22:2007+A1:2012 IEC 60825-1:2014	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 60825-1:2014 Safety of laser products - Part 1: Equipment classification, and requirements
• 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

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, "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.

8. Conclusions

The non-clinical data support the safety of the device and the software verification and validation demonstrate that the Medical Diode Laser (Model: L2) 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 (Model: L2) is substantially equivalent to the predicate device.