March 31, 2023

Wuhan Pioon Technology Co.,Ltd.
Feng Zhang
Official Primary Correspondent and Management Representative
7th Floor, A21 of Sino Pharm Building,
Biolake Innovation Park, No.666 Gaoxin Avenue
Wuhan, Hubei 430075
China

Re: K230274
Trade/Device Name: Medical Diode Laser (M2)
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 30, 2023
Received: February 1, 2023

Dear Feng Zhang:

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.

Submission Number *(if known)*

K230274

Device Name

Medical Diode Laser (M2)

Indications for Use *(Describe)*

Medical Diode Laser is intended to incision,excision,ablation,vaporization, hemostasis and/or coagulation of soft tissue.

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.

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510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K230274

I. Submitter

Device Submitter: Wuhan Pioon Technology Co.,Ltd.
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
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E-mail: zhangfeng@pioon.com

Date Prepared: December 8, 2022

II. Device

Type of 510(k): Traditional
Trade name: N/A,
Device name: Medical Diode Laser, Model: M2
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

III. Predicate Device

Fotona SkyPulse Laser Platform (K193656), 1940nm Diode Laser.
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. Device Description

The Medical Diode Laser use a wavelength 1940nm 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: M2) 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.

V. Indications for Use

Medical Diode Laser is intended to incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue.

VI. Comparison of Technological Characteristics with the Predicate Device

The predicated device is Fotona SkyPulse Laser Platform (K193656), a 1940nm Diode Laser with same intended use as the subject device.

Item	Subject device (this submission)	Predicated device (K193656)
Product Code	GEX	GEX
Regulation NO.	21 CFR 878.4810	21 CFR 878.4810
Class	II	II
Indications for Use	Medical Diode Laser is intended to incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue.	Medical Diode Laser is intended to incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue.
Use of device	RX only	RX only
Energy source	Solid state diode	Solid state diode
Configuration	Main Unit	Main Unit
	Foot Control	Foot Control
Laser Wavelength	1940nm	1940nm
Laser Classification	Class IV	Class IV
Power range	Up to 7.5W	Up to 7.5W
Pulse width	CW or 10 ms – 10 s	CW or 10 ms – 10 s
Repetition rate	CW or up to 100 Hz	CW or up to 100 Hz
Delivery system	Fiber delivery	Fiber delivery
User interface	Touch screen control	Touch screen control

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

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the Medical Diode Laser and optical fibers. The Medical Diode Laser complies with the IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-2-22:2019 and IEC 60825-1:2014 standards for safety and the IEC 60601-1-2:2014+A1:2020 standard for EMC.

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.

Summary
Based on the clinical performance, technological characteristics and performance data as documented in the submission, the Medical Diode Laser was found to have a safety and effectiveness profile that is same as the predicate device.

VIII. Conclusions

Based on its technical characteristics, performance test data, and its indications for use as above summary, we conclude that the subject device is as safe and effective as the predicate device.

Animal or clinical studies: None