April 4, 2025

Wuhan Pioon Technology Co.,Ltd.
Tracy Liu
Regulatory Affairs
12th Floor, Building 1, Innovative Unit, R&D Center Project,
Marine World Shipyard Park, No. 16 Fozuling 3rd Road, East L
Wuhan, Hubei 430205
China

Re: K250656
Trade/Device Name: Medical Diode Laser (Models: MZ-GK, MZ-K20, MZ-N75)
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: March 3, 2025
Received: March 5, 2025

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.

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: 2025.04.04 18:11:24 -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.

510(k) Number *(if known)*
K250656

Device Name
Medical Diode Laser (Models: MZ-GK, MZ-K20, MZ-N75)

Indications for Use *(Describe)*
The Medical Diode Laser (Model: MZ-GK) is 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, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Medical Diode Laser (Model: MZ-GK) is further indicated for laser assisted lipolysis.

The Medical Diode Laser (Model: MZ-K20) is indicated for:
-Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue.
-Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux.

The Medical Diode Laser (Model: MZ-N75) 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

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: **K250656**

1. Submitter

Device Submitter: Wuhan Pioon Technology Co., Ltd.
Address:12th Floor, Building 1, Innovative Unit, R&D Center Project, Marine World Shipyard Park, No. 16 Fozuling 3rd Road, East Lake High-tech Development Zone, 430205, Wuhan, Hubei,China
Tel: +86 27 81783687

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

Date Prepared: April 3, 2025

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

2. Device

Type of 510(k) submission: Special
Device name: Medical Diode Laser (Models: MZ-GK, MZ-K20, MZ-N75)
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

Item	Predicate Device 1	Predicate Device 2	Predicate Device 3
510(k) Number	K240747	K240179	K230274

Device Name	Medical Diode Laser (M2-GK)	Medical Diode Laser (Model:L2)	Medical Diode Laser (M2)
Submitter	Wuhan Pioon Technology Co., Ltd.	Wuhan Pioon Technology Co., Ltd.	Wuhan Pioon Technology Co., Ltd.
Product Code	GEX	GEX	GEX

The predicates have not been subject to a design-related recall.
No reference devices were used in this submission.

4. Device Description

The Medical Diode Laser (Models: MZ-GK, MZ-K20, MZ-N75) incorporates a solid state diode as laser energy source for producing its therapeutic effects, it is designed to deliver continuous or pulsed, infrared laser energy at wavelengths of 980nm and 1470nm respectively for MZ-GK, 1470nm for MZ-K20 and 1940nm for MZ-N75. The device also incorporates a red (650nm) or green(532nm) aiming beam diode to indicate the area to be irradiated by the laser beam. The device is composed of the main unit, foot switch, power cord, and protective goggles. The device incorporates an LCD touchscreen for the device user to set output parameters and for control of the device. The device transmits the laser output via third-party optical fibers with SMA905 connectors and with single cores of 200μm, 300μm, 400μm, 600μm, 800μm and 1000μm diameter respectively.

5. Indications for Use

The Medical Diode Laser (Model: MZ-GK) is 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, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Medical Diode Laser (Model: MZ-GK) is further indicated for laser assisted lipolysis.

The Medical Diode Laser (Model: MZ-K20) is indicated for:
-Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue.
-Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux.

The Medical Diode Laser (Model: MZ-N75) is intended to incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue.

6. Comparison to the Predicate Device

The Medical Diode Laser (Models: MZ-GK, MZ-K20, MZ-N75), has been compared to the Medical Diode Laser (Model: M2-GK) (K240747), Medical Diode Laser (Model: L2) (K240179)

and Medical Diode Laser (Model: M2)(K230274) respectively as reference for substantial equivalence. A table comparing the predicate devices to the subject device is shown as the following:

Item	**Subject Device (this submission)**	**Predicate Device 1 (K240747)**	**Predicate Device 2 (K240179)**	**Predicate Device 3 (K230274)**
Trade Name	Medical Diode Laser	Medical Diode Laser	Medical Diode Laser	Medical Diode Laser
Model	MZ-GK, MZ-K20, MZ-N75	M2-GK	L2	M2
Product Code	GEX	GEX	GEX	GEX
Regulation NO.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Class	II	II	II	II
Indications for Use	The Medical Diode Laser (Model: MZ-GK) is 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, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures,	The Medical Diode Laser(Model: M2-GK) is 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, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and	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.	Medical Diode Laser is intended to incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue.

	Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Medical Diode Laser (Model: MZ-GK) is further indicated for laser assisted lipolysis. The Medical Diode Laser (Model: MZ-K20) is indicated for: -Incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue. -Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Medical Diode Laser (Model: MZ-N75) is intended to incision, excision, ablation, vaporization, hemostasis and/or coagulation of soft tissue.	Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Medical Diode Laser (Model: M2-GK) is further indicated for laser assisted lipolysis.		
Use of Device	Rx only	Rx only	Rx only	Rx only
Laser Type	Diode laser	Diode laser	Diode laser	Diode laser
Laser Classification	Class IV	Class IV	Class IV	Class IV
Configuration	Main Unit	Main Unit	Main Unit	Main Unit

	Foot Control	Foot Control	Foot Control	Foot Control
Laser Wavelength	MZ-GK: 980nm, 1470nm MZ-K20: 1470nm MZ-N75: 1940nm	980nm 1470nm	1470nm	1940nm
Max Power	MZ-GK: 30W-980nm, 15W-1470nm MZ-K20: Up to 20W MZ-N75: Up to 7.5W	30W-980nm 15W-1470nm	Up to 20W	Up to 7.5W
Operation Mode	CW and Pulse	CW and Pulse	CW and Pulse	CW and Pulse
Pulse Duration	MZ-GK: 10 ms – 1s MZ-K20: CW or 10 ms – 10 s MZ-N75: CW or 10 ms – 10 s	10 ms – 1s	CW or 10 ms – 10 s	CW or 10 ms – 10 s
Repetition Rate	MZ-GK: 0.5 to 50 Hz MZ-K20: CW or up to 100 Hz MZ-N75: CW or up to 100 Hz	0.5 to 50 Hz	CW or up to 100 Hz	CW or up to 100 Hz
Aiming Beam	Green 532nm (<2mW)/Red 650nm (<2mW)	Red 650nm (<2mW)	Red 650nm (<2mW)	Red 650nm (<2mW)
Cooling Method	Air cooling	Air cooling	Air cooling	Air cooling
Delivery System	Fiber delivery	Fiber delivery	Fiber delivery	Fiber delivery
User Interface	Color LCD touch screen	Color LCD touch screen	Color LCD touch screen	Color LCD touch screen
Microprocessor Control	Yes	Yes	Yes	Yes
Power Supply	100-240VAC, 50/60Hz, 4A-2A	100-240VAC, 50/60Hz, 4A-2A	100-240VAC, 50/60Hz, 4A-2A	100-240VAC, 50/60Hz, 4A-2A
Dimensions &Weight	28.8cm (L) x 27.8cm (W) x11.5cm (H) ≤5 Kg.	29cm (L) x 25cm (W) x13cm (H) ≤8 Kg.	29cm (L) x 25cm (W) x13cm (H) ≤8 Kg.	29cm (L) x 25cm (W) x13cm (H) ≤8 Kg.

Safety Feature	Complied with: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-22 IEC 60825-1	Complied with: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-22 IEC 60825-1	Complied with: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-22 IEC 60825-1	Complied with: IEC 60601-1 IEC 60601-1-2 IEC 60601-2-22 IEC 60825-1

The subject device MZ-GK, MZ-K20 and MZ-N75 is a modification of the legally marketed predicate devices, M2-GK (K240747), L2 (K240179) and M2 (K230274) respectively. The subject device uses same 980nm, 1470nm and 1940nm diode lasers technology as that used by the predicates. The output parameters of the proposed device are same as the output parameters of the predicates, and subtle differences discussed below do not raise new types of questions regarding the safety and effectiveness when the device is used for the proposed indications for use. The indications for use of the subject device are nearly the same as those from each of the predicate devices and also do not raise new types of questions regarding safety and effectiveness.

The differences in technical characteristics between the devices are:

(1) Aiming Beam

The subject device has two types of aiming beam type, green(532nm) or red(650nm) light configured according to the selected laser module. Only the aiming beam type for the proposed device is different from the predicate devices. However, the aiming beam power of the proposed device is within the range of that of the predicate device, and it has been designed to meet the intended use requirement claimed. Aiming laser energy density is low and safety is guaranteed, all products meet the same standard IEC60601-1, IEC60601-1-2, IEC60601-2-22 and IEC60825-1, not affect safety and effectiveness.

(2) Dimensions &Weight

The proposed device is different in dimension and weight from the predicate devices. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted, therefore, this difference will not affect the substantially equivalency.

Based upon the aforementioned information, the differences between the subject device and predicate devices do not affect the basic design principle, usage, effectiveness, and safety of the subject device.

7. Performance Data

Clinical data:

Not applicable.

Non-clinical data:

Electrical Compatibility and Electrical Safety

The Medical Diode Laser was tested and found to conform to the criteria of the following performance standards:

• 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

The Guidance Document, Laser Products – Conformance with IEC 60825-1 and IEC 60601-2-22 (Laser Notice 56) January 19, 2018 was used. 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 specifications and meets 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 proposed Medical Diode Laser (Models: MZ-GK, MZ-K20, MZ-N75) device, and the software verification and validation demonstrate that the device can perform as intended. The proposed device uses similar laser diode technology as that used by the predicate devices and difference in parameters do not raise new types of questions regarding safety and effectiveness for the proposed indications for use. The Medical Diode Laser (Models: MZ-GK, MZ-K20, MZ-N75) is considered to be substantially equivalent to the predicate devices.