July 25, 2025

Zhengzhou PZ Laser Slim Technology Co., Ltd.
Xiaojie Shi
RA
Room 201, 2nd Floor, Building 2, No.52 Hongsong Road
High-tech Development Zone, 450001
China

Re: K251339
Trade/Device Name: Medical Diode Laser Hair Removal Device (PZ-606VI, PZ-BDT68-01, PZ-BDT68-02, PZ-BDT68-03, PZ-BDT68-04)
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: April 21, 2025
Received: April 30, 2025

Dear Xiaojie Shi:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.07.25 12:10:49 -04'00'

for 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)*
K251399

Device Name
Medical Diode Laser Hair Removal Device (PZ-606VIPZ-BDT68-01, PZ-BDT68-02, PZ-BDT68-03, PZ-BDT68-04)

Indications for Use *(Describe)*
The Medical Diode Laser Hair Removal Device (PZ-606VIPZ-BDT68-01, PZ-BDT68-02, PZ-BDT68-03, PZ-BDT68-04) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

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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The assigned 510(k) Number: K251399

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1. Date of preparation: 07/24/2025

2. Sponsor Identification:

Zheng zhou PZ Laser Slim Technology Co., Ltd.

Room 201, 2nd Floor, Building 2, No. 52 Hongsong Road, High-tech Development Zone, 450001, Zhengzhou City, Henan Province, P. R. China.

Contact Person: Xiaojie Shi

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3. Designated Submission Correspondent

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Contact Person: Xiaojie Shi

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Fax:+86-0371-55677886

Email: shixiaojie1225@163.com

4. Identification of Proposed Device

Trade Name: Medical Diode Laser Hair Removal Device

Models: PZ-606VI、PZ-BDT68-01、PZ-BDT68-02、PZ-BDT68-03、PZ-BDT68-04

Common Name: Powered Laser Surgical Instrument

Regulatory Information

Classification Name: Powered Laser Surgical Instrument

Classification: II

Product Code: GEX

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.

Review Panel: General& Plastic Surgery

Intended Use:

The Medical Diode Laser Hair Removal Device (PZ-606VI、PZ-BDT68-01、PZ-BDT68-02、PZ-BDT68-03、PZ-BDT68-04) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.

Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

5. Device Description:

The proposed device, Medical Diode Laser Hair Removal Device (PZ-606VI、PZ-BDT68-01、PZ-BDT68-02、PZ-BDT68-03、PZ-BDT68-04), is a surgical device, which is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI);

The device incorporates a diode laser that emits invisible infrared laser radiation centered on a wavelength of 808 nm. According to the selective light absorption theory, the laser can be preferentially absorbed by the melanin in the hair follicle, thus achieving the purpose of permanent hair removal. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. Hair growth must remain stable for a certain amount of time and must exceed the entire growth cycle of the hair follicle. Permanent hair removal does not mean that all hair in the treated area is completely lost. Special cooling technology is applied simultaneously during treatment to cool the skin and protect skin.

There are 5 models included, PZ-606VI, PZ-BDT68-01, PZ-BDT68-02, PZ-BDT68-03 and PZ-BDT68-04, the five models have the same intended use, mechanism of action and principle, only the minimum values of energy density and pulse duration are different. The detailed difference shown as following:

Table 1 The difference of Models

Model	Wavelength	Laser emitter	Pulse width（Pulse duration) (±10%)	Energy density (±20%)
PZ-606VI	808nm±10nm (Handle 1)	1000W 12*12 laser treatment head	3-108ms	(2-50) J/cm^2
		1000W Φ6mm treatment head	4-44ms	(3-30) J/cm^2
	808nm±10nm (Handle 2)	2000W 12*12 laser treatment head	3-80ms	(3-95) J/cm^2
		2000W 12*24 laser treatment head	3-80ms	(2-55) J/cm^2
		2000W Φ6mm treatment head	3-22ms	(3-30) J/cm^2
PZ-BDT68-01	808nm±10nm (Handle 1)	1000W 12*12 laser treatment head	6-108ms	(5-50) J/cm^2
		1000W Φ6mm treatment head	7-44ms	(5-30) J/cm^2
	808nm±10nm (Handle 2)	2000W 12*12 laser treatment head	4-80ms	(5-95) J/cm^2
		2000W 12*24 laser treatment head	8-80ms	(5-55) J/cm^2
		2000W Φ6mm treatment head	5-22ms	(5-30) J/cm^2
PZ-BDT68-02	808nm±10nm (Handle 1)	1000W 12*12 laser treatment head	12-108ms	(10-50) J/cm^2
		1000W Φ6mm treatment head	15-44ms	(10-30) J/cm^2
	808nm±10nm (Handle 2)	2000W 12*12 laser treatment head	9-80ms	(10-95) J/cm^2
		2000W 12*24 laser treatment head	15-80ms	(10-55) J/cm^2
		2000W Φ6mm treatment head	8-22ms	(10-30) J/cm^2
PZ-BDT68-03	808nm±10nm (Handle 1)	1000W 12*12 laser treatment head	3-108ms	(2-50) J/cm^2
		1000W Φ6mm treatment	7-44ms	(5-30) J/cm^2

		head		
	808nm±10nm (Handle 2)	2000W 12*12 laser treatment head	3-80ms	(3-95) J/cm^2
		2000W 12*24 laser treatment head	3-80ms	(2-55) J/cm^2
		2000W Φ6mm treatment head	5-22ms	(5-30) J/cm^2
PZ-BDT68-04	808nm±10nm (Handle 1)	1000W 12*12 laser treatment head	3-108ms	(2-50) J/cm^2
		1000W Φ6mm treatment head	15-44ms	(10-30) J/cm^2
	808nm±10nm (Handle 2)	2000W 12*12 laser treatment head	3-80ms	(3-95) J/cm^2
		2000W 12*24 laser treatment head	3-80ms	(2-55) J/cm^2
		2000W Φ6mm treatment head	8-22ms	(10-30) J/cm^2

6. Identification of Predicate Device and reference devices

Predicate device:
510(k) Number: K161692
Product Name: Diode Laser Therapy Machine
Manufacturer: Beijing ADSS Development Co., Ltd

Reference device1:
510(k) Number: K140009
Product Name: The Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano^{XL}, Soprano^{XLi} and Soprano^{ICE}]
Manufacturer: Alma Lasers Ltd

Reference device2:
510(k) Number: K210663
Product Name: Dermatological Diode Laser Systems
Manufacturer: Beijing HuaCheng Taike Technology Co., Ltd.

Reference device3:
510(k) Number: K141973
Product Name: Diode Laser Hair Removal System L808
Manufacturer: Beijing Anchorfree Technology Company Ltd.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2005+A1:2012+A2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
IEC 60601-1-2:2014+A1:2020, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic - Requirements and tests;
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
ISO 10993-5:2009, Biological Evaluation of Medical Devices, Part 5-Tests for in Vitro cytotoxicity.
ISO 10993-10:2021, Biological Evaluation of Medical Devices, Part 10-Tests for skin sensitization
ISO 10993-23:2021, Biological Evaluation of Medical Devices-Part 23: Tests for irritation.
Performance Testing for Spot Size Accuracy and Energy Output Accuracy.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 2 General Comparison

Item	Proposed Device	Predicate Device	Remark
Product Code	GEX	GEX	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Same
Intended Use	The Medical Diode Laser Hair Removal Device is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	The Diode Laser Therapy Machine is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.	Same
Configuration	Main Unit	Main Unit	Same
	Handle	Handpiece	Same
	Handle Button	Foot Control	Difference 1

Principle of Operation	Diode Laser	Diode Laser	Same
Laser Type	Diode Laser	Diode Laser	Same
Laser Classification	Class IV	Class IV	Same
Laser Wavelength	808nm	808nm	Same
Spot Size	1.44cm^2	1.44cm^2	Same
	2.88cm^2		Difference 2
	0.28cm^2		
Energy Density (Fluence)	(1)1000W 12*12 treatment head: (2-50) J/cm^2 (2)1000W Φ6mm treatment head: (3-30)J/cm^2 (3)2000W 12*12 treatment head: (3-95)J/cm^2 (4)2000W 12*24 treatment head: (2-55)J/cm^2 (5)2000W Φ6mm treatment head: (3-30)J/cm^2	2-120J/cm^2	Difference 3
Frequency	(1)1-10Hz (2)1-3Hz	1-10Hz	Same
Pulse Duration	(1)1000W 12*12 laser treatment head: 3-108ms (2)1000W Φ6mm treatment head: 4-44ms (3)2000W 12*12 laser treatment head: 3-80ms (4)2000W 12*24 laser treatment head: 3-80ms (5)2000W Φ6mm treatment head: 3-22ms	9-143ms	Difference 4
Power Supply	AC100-240V 50/60Hz	AC 110V/50Hz-60Hz	Difference 5
Dimension	550mm*550mm*1700mm	56*46*112 cm	Difference 6
		42*63*54cm	
		56*46*110cm	
		59*59*146 cm	
Weight	68kg	49kg	Difference 7
		30kg	
		45kg	
		45kg	

Analysis:

Difference1:

The predicate device emits laser through Foot Control; The proposed device emits laser through Handle Button. By complying with IEC 60601-1, the performance of the proposed device is determined to be accepted, therefore, this difference will not affect the effectiveness and safety.

Difference 2:
The spot size of the subject device (1.44cm^2, 2.88 cm^2, and 0.28 cm^2) differs from predicate device (1.44cm^2).
For the small spot size (0.28 cm^2), which is the same as the spot size of the 6mm round tapered light guide tip in K140009, the round area is calculated to be 0.28 cm^2, it is the same as that of the subject device.
The large spot size (2.88 cm^2) is similar to the spot size (3 cm^2) of CM01D in K210663, and the spot size of the proposed device is slightly smaller than 3 cm^2.
So we think this minor difference between proposed device and predicate device will not affect the effectiveness and safety. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

Difference 3:
The proposed device has different Fluence from the predicate device. The fluence of the proposed device is within the range of the predicate device, which can justify that the difference in the parameter of fluence will not raise new safety issues of the proposed device. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured. And we think this minor difference will not affect the effectiveness and safety.

Difference 4:
The proposed device has different pulse duration from the predicate device (K161692). The pulse duration of the predicate device is 9-143ms, and the pulse duration of the subject device is 3-108ms. The pulse duration between the proposed device and the predicate device only with minor difference. The K141973 (pulse duration 2.9-348ms) as a scientifically valid justification that extending the pulse duration of the proposed device to 3-108ms is as safe and effective as the predicate device, and the K141973 has the same indication for use with predicate device will not affect the effectiveness and safety. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

Difference 5：
The power supply for the proposed device is different from the predicate device. However, electrical safety and EMC test has been conducted on the proposed device and the test result show that the device can work normally under this power supply. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Difference 6:

The proposed device is different in dimension from the predicate device. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted, therefore, this difference of dimension have no effect the effectiveness and safety.

Difference 7:
The proposed device is different in weight from the predicate device. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted, therefore, this difference of weight have no effect the effectiveness and safety.

Table 3 Safety Comparison

Item	Proposed Device	Predicate Device	Remark
Patient Contact Materials and Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No evidence of sensitization	No evidence of sensitization	Same
Irritation	No evidence of irritation	No evidence of irritation	Same
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	Same

10. Substantially Equivalent (SE) Conclusion
Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.