October 23, 2025

Zhengzhou PZ Laser Slim Technology Co., Ltd
Yueming Li
Regulatory Affairs Specialist
3rd Floor, Building 1, No. 101 Jinbai Road, High-tech
Dev. Zone, 450001 Zhengzhou City, Henan Province
Zhengzhou,
China

Re: K252732
Trade/Device Name: 1927nm Thulium Laser System (PZ-DJG75-01, PZ-DJG75-02)
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: August 28, 2025
Received: August 28, 2025

Dear Yueming Li:

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: 2025.10.23 12:52:49 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252732

Please provide the device trade name(s).

1927nm Thulium Laser System (PZ-DJG75-01, PZ-DJG75-02)

Please provide your Indications for Use below.

1927nm Thulium Laser System is indicated for use in dermatological procedures requiring coagulation of soft tissue, treatment of actinic keratosis and treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

The assigned 510(k) Number: K252732

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**: 08/28/2025

2. **Sponsor Identification:**

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3. **Designated Submission Correspondent**

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4. **Identification of Proposed Device**

Trade Name: 1927nm Thulium Laser System

Models: PZ-DJG75-01, PZ-DJG75-02

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: 1927nm thulium laser system is indicated for use in dermatological procedures requiring coagulation of soft tissue, treatment of actinic keratosis and treatment of benign pigmented lesions such as, but not limited to, lentigos(age spots), solar lentigos (sun spots)and ephelides (freckles).

5. Device Description

1927nm Thulium Laser System contains a thulium-doped fiber laser module that uses a 1927nm pulsed laser output energy. The beam is directly irradiated to the treatment area through the handle and optical fiber. According to the selective light absorption theory, the1927nm laser can be preferentially absorbed by the water in the skin, thus achieving the purpose of coagulation of soft tissue.

The operator can optimize the treatment effect of each application by controlling the pulse width, distance between the dot matrices and treatment mode of the pulsed laser.

There are 2 models included, PZ-DJG75-01, PZ-DJG75-02, the two models have the same intended use, mechanism of action and principle, only the step of pulse width under the dot matrix mode are different. The detailed differences shown as following:

Table 1 The differences between two models

Model	Wavelength	Mode	Pulse width (±20%)	Step
PZ-DJG75-01	1927nm±10nm	Slide	0.2-2.0ms	0.1ms
		Dot matrix	0.2-20.0ms	0.1ms
PZ-DJG75-02	1927nm±10nm	Slide	0.2-2.0ms	0.1ms
		Dot matrix	0.2-20.0ms	0.2ms

6. Identification of Predicate Device

510(k) Number: K241406

Product Name: Lavieen

Manufacturer: WON TECH Co., Ltd

7. Identification of Reference Device

510(k) Number: K182173

Product Name:JOULE 1927nm Laser System

Manufacturer:Sciton, Inc

8. 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 60601-1:2020 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.

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.

IEC 60601-1-2:2020, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic disturbances- Requirements and tests.

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.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10.Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device	Predicate Device	Reference Device	
Device Name	1927nm Thulium Laser System	Lavieen	JOULE 1927nm Laser System	/
Classification regulation	21CFR 878.4810	21CFR 878.4810	21CFR 878.4810	Same
Classification Panel	General&Plastic Surgery	General&Plastic Surgery	General&Plastic Surgery	Same
class	II	II	II	Same
Product Code	GEX	GEX	GEX	Same
Common name	Powered laser surgical instrument	Powered laser surgical instrument	Powered laser surgical instrument	Same
Indication for use	1927nm thulium laser system is indicated for use in dermatological procedures requiring coagulation of soft tissue, treatment of actinic keratosis and treatment of benign pigmented lesions such as, but not limited to, lentigos	Lavieen is indicated for use in dermatological procedures requiring coagulation of soft tissue, treatment of actinic keratosis and treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots) and ephelides	JOULE 1927nm Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun	Same

	(age spots), solar lentigos (sun spots) and ephelides (freckles).	(freckles).	spots) and ephelides (freckles).	
Prescription use or not	Prescription use	Prescription use	Prescription use	Same

Table 2 Performance comparison

Item	Proposed device	Predicate device	Reference Device	
Laser Type	Thulium laser	Thulium laser	Thulium laser	Same
Laser Wavelength	1927nm	1927nm	1927nm	Same
Aiming Beam	658nm, ＜5mW	658nm	--	Same
Beam delivery	Fiber and Handpiece	Fiber and Handpiece	Articulated arm and Handpiece	Same
Emission control	Foot Switch	Foot Switch	Foot Switch	Same
Laser power	10W	10W	12W	Same
Pulse Duration (Pulse Width)	0.2-20ms	0.1-20ms	Up to 20ms	Same
Pulse Repetition Rate(Frequency)	45Hz-445Hz	67-240Hz	0-3 kHz	Same
Spot Size	300μm	300μm	100-620μm	Same

SE Analysis:

The spot size of proposed device and predicate device is 300 μm. The maximum single-pulse energy is 20mJ, which is related to the output power and pulse width., and the maximum energy density is $20/(0.15^2\pi)=282.9$mJ/mm2.

The radiation energy in the treatment area is the product of the single pulse energy and the number of pulses, which is related to the spot spacing.

These parameters related to clinical use are exactly the same as the predicate device.

Compared with predicate device, the range of pulse repetition frequency of the Proposed device is slightly larger.

$$\text{Frequency}=\frac{1}{(\text{Pulse width}+\text{Delay})}$$

Setting a smaller delay, pulse frequency will increase, but at the same time can reduce the single dot matrix output time, will reduce the total operation time in clinical use. In conclusion, the pulse repetition rate does not affect the safety and effectiveness of device use.

In order to further confirm the rationality of the declared device pulse repetition frequency, a reference device was selected with a pulse repetition frequency range of 1-3kHz. The pulse repetition rate of proposed device is within its scope.

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

11.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 K241406.