August 27, 2026

Zhengzhou PZ Laser Slim Technology Co., Ltd.
Xiaopei Zhao
Regulatory Affairs Specialist
3rd Floor, Bldg. 1, # 101 Jinbai Rd., High-Tech Development Zone, 450001 Zhengzhou City, Henan Province, People'S Republic Of China.
Zhengzhou,
China

Re: K261821
Trade/Device Name: 1565nm Laser Therapy Device (PZ-JG86-01,PZ-JG86-02)
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: May 30, 2026
Received: June 1, 2026

Dear Xiaopei Zhao:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.08.27 18:13:56 -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

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.	K261821

Please provide the device trade name(s).

1565nm Laser Therapy Device (PZ-JG86-01,PZ-JG86-02)

Please provide your Indications for Use below.

The 1565nm Laser Therapy Device is indicated for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue, and improving the appearance of scalp hair in adult males and females with Fitzpatrick skin type I to IV who are seeking treatment for hair loss.

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

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [x] Adolescents (12 years old to < 22 years old)
- [x] Adults (22 years old and greater)

The assigned 510(k) Number: **K261821**

510(k) Summary

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

1. Date of preparation: 05/27/2026

2. Sponsor Identification

Zhengzhou PZ Laser Slim Technology Co., Ltd.

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: 1565nm Laser Therapy Device

Models: PZ-JG86-01, PZ-JG86-02

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: The 1565nm Laser Therapy Device is indicated for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue, and improving the appearance of scalp hair in adult males and females with Fitzpatrick skin type I to IV who are seeking treatment for hair loss.

5. Device Description

1565nm Laser Therapy Device is Er:Glass Fiber-laser with scanner laser system that generate laser beams at 1565nm wavelengths. The 1565nm Laser Therapy Device is mainly composed of a host, a treatment handle, two treatment tips, a foot switch and a power cord. The treatment tip, intended for direct patient contact, is made of medical-grade aluminum alloy with gold-plated surface.

Its principle of operation is based on the theory of Selective Photothermolysis and Fractional Laser Technology.

These two models are completely identical in terms of their product principles, structure and composition, intended use, key components, and electrical structure, with only the Scanner shapes are different.

6. Identification of Predicate Device

510(k) Number: K222790

Product Name: F65 Laser System

Manufacturer: Lumenis Be Ltd.

7. Comparison of technological characteristics with the predicate devices

Table 1 General Comparison

Description	Proposed Device	Predicate Device	Comparison
Device Name	1565nm Laser Therapy Device	F65 Laser System（F1565nm module）K222790	/
Classification regulation	21CFR 878.4810	21CFR 878.4810	Same
Classification Panel	General&Plastic Surgery	General&Plastic Surgery	Same
class	II	II	Same
Product Code	GEX	GEX	Same
Common name	Powered laser surgical instrument	Powered laser surgical instrument	Same

Indication for use	The 1565nm Laser Therapy Device is indicated for use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue, and improving the appearance of scalp hair in adult males and females with Fitzpatrick skin type I to IV who are seeking treatment for hair loss.	The F65 module and hand piece, with wavelength of 1565 nm, are indicated for: Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue ; Improving the appearance of scalp hair in adult males and females with Fitzpatrick skin type I to IV who are seeking treatment for hair loss.	Same
Principle of Operation	Selective photothermolysis, fractional laser technology	Selective photothermolysis, fractional laser technology	Same
Prescription use or not	Prescription use	Prescription use	Same

Table 2 Performance comparison

Description	**Proposed device**	**Predicate device**	**Comparison**
Device Name	1565nm Laser Therapy Device	F65 Laser System（F1565nm module）K222790	/
Type of Laser	Er:Glass Fiber-laser with scanner	Er:Glass Fiber-laser with scanner	Same
Laser Wavelength	1565nm	1565nm	Same
Beam density	Up to 500 micro beams per cm^2	up to 500 micro beams per cm^2	Same
Energy	10mJ-70mJ per micro beam	Up to 70 mJ per micro beam	Same

Tip treatment width	Up to 18mm	Up to 18mm	Same
Max pulse width	10ms	10ms	Same
Scanner shapes	Square, circle, ring, regular hexagon, horizontal line, vertical line, horizontal rectangle, vertical rectangle.	Line, square, rectangle, circle, donut, hexagon, vertical line, and vertical rectangle	Same
Aiming beam Laser Wavelength	650nm	650nm	Same

SE Analysis:

proposed device is compared only with the F1565nm module of the predicate device (K222790). The comparative analysis results show that the proposed device is consistent with the F1565nm module of the predicate device (K222790) in key performance metrics such as intended use, laser wavelength, laser type, beam density, energy density, tip treatment width, and scanner shape. Although the predicate device contains multiple modules, each module has a different intended use and can operate independently without interfering with one another. Therefore, the proposed device is equivalent to the F1565nm module of the predicate device (K222790); the proposed device is substantially equivalent to the predicate device.

8. Performance data

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

1）Electrical Safety, Electromagnetic Compatibility Testing

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.

2）Biocompatibility

Biocompatibility tests were conducted to verify if the proposed device meets safety and effectiveness criteria. The test results indicate that the proposed device complies with the following standards:

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/Amd1：2025, Biological Evaluation of Medical Devices-Part 23: Tests for irritation.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. **Conclusions**

Proposing differences between the device and the predicate device will not raise new safety and effectiveness-related issues. The proposed device is identical to the legally marketed predicate device (K222790) in terms of intended use, key technical characteristics (such as laser wavelength, energy, beam density), etc. Furthermore, the proposed device has been verified through electromagnetic compatibility, electrical safety, and biocompatibility testing. Therefore, the safety and effectiveness of the proposed device are equivalent to those of predicate device K222790.