June 12, 2025

Zhengzhou PZ Laser Slim Technology Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401
China

Re: K250782
Trade/Device Name: Fractional CO2 Laser Machine
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, ONG
Dated: March 14, 2025
Received: March 14, 2025

Dear Ray Wang:

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: 2025.06.12 12:12:20 -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.

Submission Number *(if known)*

K250782

Device Name

Fractional CO2 Laser Machine

Indications for Use *(Describe)*

- CO2 LASER Part:
Fractional mode is indicated only for ablative skin resurfacing.
Non-fractional mode (Impulse mode) is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otorhinolaryngology (ENT), gynecology, neurosurgery, dental and oral surgery and genitourinary surgery.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

The assigned 510(k) Number: K250782

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 Title 21, CFR Section 807.92.

1. Date of Preparation:2025/02/25

2. Sponsor Identification

Zhengzhou 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: Hongwei Zhou
Position: General Manager
Tel: +86-18736013788
Fax: 0371-55677868
Email: 565107678@qq.com

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, 102401, China

Tel: +86-18910677558
Email: information@believe-med.com

4. Identification of Proposed Device

Trade Name: Fractional CO2 Laser Machine

Common Name: Powered Laser Surgical Instrument, Powered Laser Surgical Instrument With Microbeam\Fractional Output

Regulatory Information
Classification Name: Powered Laser Surgical Instrument, Powered Laser Surgical Instrument With Microbeam\Fractional Output
Classification: II
Product Code: GEX, ONG
Regulation Number: 878.4810
Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

510(k) Number: K172096
Product Name: Ilooda Fraxis CO2 Laser
Manufacturer: Ilooda Co. LTD

6. Device Description

The Fractional CO2 Laser Machine uses a CO2 laser with the emission wavelength of 10600nm to emit focal spots through a high focus lens. The target is water in skin tissue. A certain amount of thermal stripping, more thermal coagulation and obvious thermal effect are produced at the part directly penetrated by the focal spot.

The Fractional CO2 Laser Machine has two operational modes, fractional mode and impulse mode.
Fractional mode includes three modes: normal, random and midsplit;
Impulse mode includes three modes: single, continuous and impulse.

The Fractional CO2 Laser Machine has 5 modules: Control display panel module, Main control power module, Light guide arm module, Fan cooling module, Laser module.

7. Indication For Use Statement:

- CO2 LASER Part:

Fractional mode is indicated only for ablative skin resurfacing.
Non-fractional mode (Impulse mode) is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otorhinolaryngology (ENT), gynecology, neurosurgery, dental and oral surgery and genitourinary surgery.

8. Substantially Equivalent (SE) Comparison

Tab 1 General Comparison

Item	Proposed Device	Predicate Device	Remark
Device Name	Fractional CO2 Laser Machine	Ilooda Fraxis CO2 Laser	/
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	SAME
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	SAME
Class	II	II	SAME
Product Code	GEX, ONG	GEX, ONG	SAME
Common Name	Powered Laser Surgical Instrument, Powered Laser Surgical Instrument With Microbeam\Fractional Output	Powered Laser Surgical Instrument, Powered Laser Surgical Instrument With Microbeam\Fractional Output	SAME
Indication for use	- CO2 LASER Part: Fractional mode is indicated only for ablative skin resurfacing. Non-fractional mode (Impulse mode) is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otorhinolaryngology (ENT), gynecology, neurosurgery, dental and oral surgery and genitourinary surgery.	- CO2 LASER Part: Fractional mode is indicated only for ablative skin resurfacing. Non-fractional mode is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otorhinolaryngology (ENT), gynecology, neurosurgery, dental and oral surgery and genitourinary surgery.	SAME
Prescription use or not	Prescription use	Prescription use	SAME

Tab 2 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark
Laser Type	CO2	CO2	SAME
Laser Wavelength	10.6 μ m	10.6 μ m	SAME
Output power	30W	30W	SAME

Pulse Duration	100-5,000μs	20-5,000μs	SAME
Fractional Pulse energy	Max 150mJ	Max 150mJ	SAME
Repetition rate	1,000Hz	1,000Hz	SAME
Scan area	20x20mm	20x20mm	SAME
Spot size	100-200μm Non-fractional: Max 1.3mm	100-200μm Non-fractional: Max 1.3mm	SAME
Number of microbeams per surface area (fractional)	Max 289 spot/cm2	Max 289 spot/cm2	SAME
Energy per microbeam (fractional)	150mJ	150mJ	SAME
Total power per surfaced area (fractional)	Max 30W	Max 30W	SAME
Treatment Time	10-15 min	10-15 min	SAME
Pulse rate (nonfractional)	1Hz – 1,000Hz	1Hz – 1,000Hz	SAME
Pulse width (nonfractional)	100μs –5000μs	20μs –5000μs	SAME
Operational mode	Fractional mode, Impulse mode (single/ continuous/ impulse)	Fractional mode, normal mode (CW, Pulse, Single Pulse)	SAME

Aiming beam	Diode laser (Red), Max 4mW	Diode laser(Red), Max 4mW	SAME
Cooling	Air cooling	Air cooling	SAME
User Interface	LCD touch screen	LCD touch screen	SAME
Optical guide	Articulate system	Articulated arm	SAME
Electrical Requirements	100-120V~, 50-60Hz	100-240VAC, 50-60 Hz, 6.3 A	Analysis
Energy flux per μ beams(mJ/cm2/pulse, mean and range)	$(4.8*10^5 \sim 1.9*10^6)$ mJ/cm^2	$(4.8*10^5 \sim 1.9*10^6)$ mJ/cm^2	SAME
Power flux per μbeam(mW/cm2/ pulse, mean and range)	$(9.5*10^7 \sim 3.8*10^8)$mW/cm^2	$(9.5*10^7 \sim 3.8*10^8)$mW/cm^2	SAME
Inter-beam spacing(mm, mean and range)	0.6mm-2.6mm	/	Analysis

Analysis:

Analysis- Electrical Requirements

The electrical requirements 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 electrical requirements. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Analysis - Inter-beam spacing

In theory, the Inter-beam spacing is determined by the diameter of the micro beams and the number of micro beams per unit area (289 spot/cm2). And because the micro beam diameter and the number of micro beams per unit area (289 spots/cm2) of the subject device are exactly the same as the predicate

device. Therefore, we believe that the Inter-beam spacing of the subject device should be the same as the predicate device.

Tab 3 Safety Comparison

ITEM	Proposed Device	Predicate Device	Remark
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Laser Safety	Comply with IEC 60601-2-22, IEC 60825-1	Comply with IEC 60601-2-22, IEC 60825-1	SAME
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SAME
Irritation	No evidence of irritation	No evidence of irritation	SAME
Sensitization	No evidence of sensitization	No evidence of sensitization	SAME

9. 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 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
- IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification, and requirements
- IEC 60601-2-22: 2012 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Fourth edition 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performance as well as the legally marketed predicate device, Ilooda Fraxis CO2 Laser cleared under K172096.