

K250782 Fractional CO2 Laser MachineJun 12, 2025
90 days to decisionK250782 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250782/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 14, 2025
Decision date	Jun 12, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhengzhou PZ Laser Slim Technology Co., Ltd.
Location	High-Tech Development Zone, Zhengzhou, CN
Contact	Hongwei Zhou
510(k) history	6 submissions · 6 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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