FDA 510(k) Premarket Notification

CLEARED

K250041 Medical Picosecond ND: YAG Laser System (PZ-6)

May 14, 2025
126 days to decision

K250041 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k250041/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 8, 2025
Decision date	May 14, 2025
Days to decision	126 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	Junmei Li
510(k) history	6 submissions · 6 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

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