

K250656 Medical Diode Laser (Models: MZ-GK, MZ-K20, MZ-N75)

Apr 4, 2025
30 days to decision

K250656 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k250656/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 5, 2025
Decision date	Apr 4, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuhan Pioon Technology Co., Ltd.
Location	Wuhan, CN
Contact	Feng Zhang
510(k) history	7 submissions · 7 cleared · 2023-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k250656/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026