

K250465 CO2 Laser Machine (Lume)Jun 9, 2025
111 days to decisionK250465 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k250465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 18, 2025
Decision date	Jun 9, 2025
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nanjing Bestview Laser S&T Co., Ltd.
Location	Nanjing, CN
Contact	Jing Wang
510(k) history	4 submissions · 4 cleared · 2024-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250465/> 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