

K250206 Diode laser system (Night UniverseApr 24, 2025
90 days to decisionK250206 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 24, 2025
Decision date	Apr 24, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Predator)

APPLICANT

Company	Ivylaser (Beijing) Technology Co.,Ltd
Location	Beijing, CN
Contact	Yuan Xiujuan
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Microkn Medical Technology Service (Shanghai) Co., Ltd.
Contact	Owen He

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250206/> 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