

K241791 Medical Diode Laser Systems (GBOX-6H, GBOX-10D , GBOX-12D, GBOX-15D, VELAS Pro-30B15D, VELAS II-6H, VELAS II-15D)Mar 19, 2025
271 days to decisionK241791 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k241791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 21, 2024
Decision date	Mar 19, 2025
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gigaalaser Company , Ltd.
Location	Wuhan, CN
Contact	Xinxing Nie
510(k) history	4 submissions · 4 cleared · 2024-2025

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