

K252515 Q-Switched Nd:Yag laser (K690)Nov 6, 2025
87 days to decisionK252515 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252515/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 11, 2025
Decision date	Nov 6, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hebei Keylaser Sci-Tech Co.,Ltd
Location	Baoding, CN
Contact	Yang Zhen
510(k) history	3 submissions · 3 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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

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