

K250018 Medical Diode Laser Systems (THEIA808)Apr 1, 2025
88 days to decisionK250018 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250018/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 3, 2025
Decision date	Apr 1, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250018/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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