

K242987 Thulium Fiber Laser (FiberLAZE+, FiberLAZE)Dec 17, 2024
82 days to decisionK242987 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242987/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 26, 2024
Decision date	Dec 17, 2024
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Allengers Global Healthcare Private Limited
Location	Derabassi, District- Mohali, IN
Contact	Harpreet Singh
510(k) history	2 submissions · 2 cleared · 2023-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242987/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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