

K252787 Thulium Fiber Laser System (TFL-A)Nov 24, 2025
83 days to decisionK252787 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 2, 2025
Decision date	Nov 24, 2025
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Thulium Fiber Laser System (TFL-B)

APPLICANT

Company	Guangzhou Potent Medical Equipment Joint-Stock Co., Ltd.
Location	Guangzhou, CN
Contact	Zhengzhou Li
510(k) history	7 submissions · 7 cleared · 2025-2026

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