

**K253007 Laser Fiber (PT-OF-A-S)**Nov 20, 2025  
62 days to decisionK253007 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253007/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 19, 2025
Decision date	Nov 20, 2025
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Laser Fiber (PT-OF-B-S); Laser Fiber (PT-OF-C-S); Laser Fiber (PT-OF-D-S); Laser Fiber (PT-OF-E-S); Laser Fiber (PT-OF-F-S)

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253007/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026