

K251303 Tamburo Thulium Fiber Laser SystemNov 4, 2025
190 days to decisionK251303 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251303/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 28, 2025
Decision date	Nov 4, 2025
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Menovex Medical Technology (Shenzhen) Co., Ltd.
Location	Shenzhen, CN
Contact	Xueying Qin
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Kyra Kang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251303/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026