

K242293 Medical Thulium Fiber Laser Systems (UroFiber 60Q)Nov 19, 2024
109 days to decisionK242293 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242293/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 2, 2024
Decision date	Nov 19, 2024
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rhein Laser Technologies Co., Ltd.
Location	Wuhan, CN
Contact	Na Wu
510(k) history	3 submissions · 3 cleared · 2024-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242293/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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