

K261738 Medical Thulium Fiber Laser Systems (UroFiber 150Q)

Jul 21, 2026
55 days to decision

K261738 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k261738/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 27, 2026
Decision date	Jul 21, 2026
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rhein Laser Technologies Co., Ltd.
Location	Wuhan, CN
Contact	Na Wu
510(k) history	4 submissions · 4 cleared · 2024-2026