

K253633 Holmium Laser Therapeutic Apparatus (HZ-40)Jan 24, 2026
66 days to decisionK253633 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 19, 2025
Decision date	Jan 24, 2026
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253633/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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