

K222369 PURE LaserOct 7, 2022
63 days to decisionK222369 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 5, 2022
Decision date	Oct 7, 2022
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Endymed Medical, Ltd.
Location	Binyamina, IL
Contact	Ohad Fisher
510(k) history	8 submissions · 7 cleared · 2011-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222369/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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