

**K242349 FoLix**Sep 9, 2024  
32 days to decisionK242349 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242349/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 8, 2024
Decision date	Sep 9, 2024
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lumenis Be, Ltd.</b>
Location	Yokneam, IL
Contact	Shlomit Segman
510(k) history	5 submissions · 5 cleared · 2022-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242349/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026