

K250809 Stellar M22Apr 16, 2025
30 days to decisionK250809 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250809/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 17, 2025
Decision date	Apr 16, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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