

K251432 OloAug 6, 2025
90 days to decisionK251432 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251432/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 8, 2025
Decision date	Aug 6, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	El.En S.P.A.
Location	Hopkinton, MA, US
Contact	Paolo Peruzzi
510(k) history	15 submissions · 15 cleared · 2014-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251432/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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