

K260489 LASEmaR 1500May 29, 2026
105 days to decisionK260489 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k260489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 13, 2026
Decision date	May 29, 2026
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eufoton S.R.L.
Location	Trieste, IT
Contact	Andrea Buoso
510(k) history	2 submissions · 2 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260489/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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