

K261094 YellowStarApr 29, 2026
27 days to decisionK261094 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k261094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 2, 2026
Decision date	Apr 29, 2026
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Asclepion Laser Technologies GmbH
Location	Chelmsford, MA, US
Contact	Tom Gruender
510(k) history	29 submissions · 29 cleared · 2004-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k261094/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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