

K250189 AdvaTxApr 1, 2025
69 days to decisionK250189 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 22, 2025
Decision date	Apr 1, 2025
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Advalight Aps
Location	North Reading, MA, US
Contact	Amogh Kothare
510(k) history	2 submissions · 2 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250189/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026