

K261964 ECHOLASER X4

Aug 19, 2026
69 days to decision

K261964 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k261964/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 11, 2026
Decision date	Aug 19, 2026
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elesta S.P.A
Location	Calenzano, IT
Contact	Alessia Blundo
510(k) history	4 submissions · 4 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	DuVal & Associates, P.A.
Contact	Jessica Czamanski

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)