

K213594 ECHOLASER X4May 3, 2022
172 days to decisionK213594 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k213594/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 12, 2021
Decision date	May 3, 2022
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Elesta S.P.A
Location	Calenzano, IT
Contact	Fabio Andreola
510(k) history	3 submissions · 3 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	Maurizio Pantaleoni
Contact	Maurizio Pantaleoni

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213594/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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