

**K230460 Laser Thermal Therapy Kit**May 22, 2023  
90 days to decisionK230460 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230460/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 21, 2023
Decision date	May 22, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Maurizio Pantaleoni</b>
Contact	Maurizio Pantaleoni

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230460/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 23, 2026