

K260632 LASER THERMAL THERAPY KITMar 17, 2026
19 days to decisionK260632 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k260632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 26, 2026
Decision date	Mar 17, 2026
Days to decision	19 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	3 submissions · 3 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	DuVal & Associates
Contact	Jenifer Ulrikson

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

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