

K231309 SCAR 3Jun 2, 2023
28 days to decisionK231309 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231309/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 5, 2023
Decision date	Jun 2, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	El.En Electroinc Engineering Spa
Location	Calenzano, IT
Contact	Paolo Peruzzi
510(k) history	1 submissions · 1 cleared · 2023-2023

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