

**K211362 SCAR 3**Aug 25, 2021  
114 days to decisionK211362 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211362/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 3, 2021
Decision date	Aug 25, 2021
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>EI.En Electronic Engineering Spa</b>
Location	Calenzano, IT
Contact	Paolo Peruzzi
510(k) history	27 submissions · 27 cleared · 2007-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211362/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026