

**K212607 Darwin**Nov 15, 2021  
90 days to decisionK212607 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212607/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 17, 2021
Decision date	Nov 15, 2021
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>Luvo Medical Technologies, Inc.</b>
Location	Cambridge, CA
Contact	Gregory Berzak
510(k) history	5 submissions · 5 cleared · 2020-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212607/> 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 26, 2026