

**K162169 EdgeOne CO2 Laser**Oct 27, 2016  
85 days to decisionK162169 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162169/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 3, 2016
Decision date	Oct 27, 2016
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jeisys Medical, Inc.</b>
Location	Littleton, CO, US
Contact	Erica Seo
510(k) history	15 submissions · 15 cleared · 2008-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162169/> 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