

**K192430 Epic 980**Dec 4, 2019  
90 days to decisionK192430 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192430/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 5, 2019
Decision date	Dec 4, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biolase, Inc.</b>
Location	Irvine, CA, US
Contact	Alicia Mszyca
510(k) history	10 submissions · 10 cleared · 2014-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192430/> 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