

**K140964 CALCULASE II**Sep 4, 2014  
142 days to decisionK140964 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k140964/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 15, 2014
Decision date	Sep 4, 2014
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>KARL STORZ Endoscopy-America, Inc.</b>
Location	Mchenry, IL, US
Contact	WINKIE WONG
510(k) history	361 submissions · 361 cleared · 1980-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140964/> 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 15, 2026