

**K140679 SUREFLEX LITHOTRIPSY LASER FIBERS**Jun 20, 2014  
94 days to decisionK140679 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k140679/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 18, 2014
Decision date	Jun 20, 2014
Days to decision	94 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Medical Systems</b>
Location	Minnetonka, MN, US
Contact	JOSH CLARIN
Website	<a href="http://www.varian.com">http://www.varian.com</a>
510(k) history	10 submissions · 10 cleared · 2008-2014

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140679/> 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 June 6, 2026