

**K944151 OPTICAL FIBER FOR ENT APPLICATIONS**Nov 1, 1994  
84 days to decisionK944151 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k944151/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 9, 1994
Decision date	Nov 1, 1994
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cardiogenes</b>
Location	Palo Alto, CA, US
Contact	DOUGLAS MURPHY-CHUTORIAN
510(k) history	20 submissions · 19 cleared · 1992-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944151/> 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 July 5, 2026