

**K943445 MEGABEAM FIBER OPTIC DELIVERY SYSTEM**Aug 26, 1994  
39 days to decisionK943445 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k943445/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 18, 1994
Decision date	Aug 26, 1994
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ceram Optec, Inc.</b>
Location	Washington, DC, US
Contact	JONATHAN S KAHAN
510(k) history	30 submissions · 30 cleared · 1992-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943445/> 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