

K943526 MEGABEAM LATERAL FIRE FIBER OPTIC DELIVERY SYSTEMAug 26, 1994
36 days to decisionK943526 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k943526/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 21, 1994
Decision date	Aug 26, 1994
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943526/> Data sourced from FDA 510(k) public records (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. - Generated July 5, 2026