

K904420 DISPOSABLE FIBER OPTIC DELIVERY SYSTEMApr 8, 1991
193 days to decisionK904420 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k904420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 27, 1990
Decision date	Apr 8, 1991
Days to decision	193 days
Third-party review	No

APPLICANT

Company	Fiber Delivery Concepts, Inc.
Location	Somerville, MA, US
Contact	JAMES P WALKER
510(k) history	4 submissions · 4 cleared · 1990-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904420/>, 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 7, 2026