

K100194 OPTICAL INTEGRITY LASERGUARD FIBERSMay 20, 2010
118 days to decisionK100194 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k100194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 22, 2010
Decision date	May 20, 2010
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Optical Integrity, Inc.
Location	Panama City Beach, FL, US
Contact	RONALD E BOWMAN
510(k) history	2 submissions · 2 cleared · 2002-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100194/> 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 June 21, 2026