

K004021 F1 DIODE LASER SYSTEMMar 27, 2001
90 days to decisionK004021 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k004021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 27, 2000
Decision date	Mar 27, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Opus Medical, Inc.
Location	Albuquerque,, NM, US
Contact	CONNIE WHITE-HOY
510(k) history	13 submissions · 13 cleared · 2001-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k004021/> 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 May 14, 2026