

K030235 F1 DIODE LASER SYSTEMApr 23, 2003
90 days to decisionK030235 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k030235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 23, 2003
Decision date	Apr 23, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Opus Medical, Inc.
Location	Albuquerque,, NM, US
Contact	RENE VAN DE ZANDE
510(k) history	13 submissions · 13 cleared · 2001-2004

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