

K003440 SOFTLASE - SURGICAL DIODE LASER SYSTEMApr 20, 2001
165 days to decisionK003440 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k003440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 6, 2000
Decision date	Apr 20, 2001
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zap Lasers, Inc.
Location	Pleasant Hill, CA, US
Contact	DAVID W SCHLERF
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003440/> 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 3, 2026