

K083069 EZLASE 10WNov 13, 2008
29 days to decisionK083069 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k083069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 15, 2008
Decision date	Nov 13, 2008
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biolase Technology, Inc.
Location	Clemente, CA, US
Contact	IOANA RIZOIU
510(k) history	31 submissions · 31 cleared · 1995-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083069/> 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 9, 2026