

**K003385 TWILITE, TWILITE WHITE**Jan 25, 2001  
86 days to decisionK003385 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k003385/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 31, 2000
Decision date	Jan 25, 2001
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003385/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026