

**K010689 MEGABEAM/CERALAS NON STERILE FIBER OPTIC  
LASER DELIVERY SYSTEMS, MODEL 200,320,400 OR 600UM**May 18, 2001  
71 days to decisionK010689 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k010689/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 8, 2001
Decision date	May 18, 2001
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biolitec, Inc.</b>
Location	East Longmeadow, MA, US
Contact	CAROL J MORELLO
510(k) history	28 submissions · 28 cleared · 2001-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010689/> 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 15, 2026