

**K113709 MEGABEAM FIBER OPTIC DELIVERY SYSTEM WITH  
ADDITIONAL TIPS & HANDPIECE**Jan 20, 2012  
32 days to decisionK113709 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k113709/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 19, 2011
Decision date	Jan 20, 2012
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biolitec Medical Devices, Inc.</b>
Location	Grandville, MA, US
Contact	HARRY HAYES
510(k) history	9 submissions · 9 cleared · 2011-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113709/>; 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 May 21, 2026