

K113688 MEGABEAM REUSABLE FIBER OPTIC DELIVERY SYSTEMMar 13, 2012
89 days to decisionK113688 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k113688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 15, 2011
Decision date	Mar 13, 2012
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113688/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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