

K112987 TWISTER SIDE FIRE OPTICAL FIBER DELIVERY SYSTEMDec 16, 2011
71 days to decisionK112987 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k112987/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 6, 2011
Decision date	Dec 16, 2011
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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