

**K061909 HIGHLAND BEAM DELIVERY SYSTEM, MODEL  
3-099-002-00-00**Jul 19, 2006  
13 days to decisionK061909 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k061909/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 6, 2006
Decision date	Jul 19, 2006
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omniguide, Inc.</b>
Location	Cambridge, MA, US
Contact	IRINA KULINETS
Website	<a href="http://www.omni-guide.com">http://www.omni-guide.com</a>
510(k) history	14 submissions · 14 cleared · 2006-2021

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