

**K061646 LASERSCOPE GUIDED DELIVERY DEVICE (GDD)  
CYSTOURETHROSCOPE & ACCESSORIES**Jun 27, 2006  
15 days to decisionK061646 · Product code: **FBO** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k061646/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystourethroscope (FBO)
Date received	Jun 12, 2006
Decision date	Jun 27, 2006
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Laserscope</b>
Location	Santa Clara, CA, US
Contact	PAUL HARDIMAN
510(k) history	60 submissions · 60 cleared · 1985-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061646/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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