

**K070197 ACUMEN LEAD DELIVERY SHEATH WITH STYLET,  
MODELS LDS-10-64-STY AND LDS-10-57-STY**Feb 23, 2007  
32 days to decisionK070197 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k070197/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jan 22, 2007
Decision date	Feb 23, 2007
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acumen Medical, Inc.</b>
Location	Mountain View, CA, US
Contact	Marybeth Gamber
510(k) history	12 submissions · 12 cleared · 2004-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070197/>; 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 June 23, 2026