

**K062145 MODIFIED ACUMEN LEAD DELIVERY SHEATH,  
MODELS LDS-10-57, LDS-10-57-90, LDS-10-64 AND  
LDS-10-64-90**Aug 23, 2006  
27 days to decisionK062145 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k062145/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 27, 2006
Decision date	Aug 23, 2006
Days to decision	27 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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