

**K070396 MODIFICATION TO: ACUMEN SINGLE-LUMEN  
DELIVERY SHEATH, MODELS BLS-8-45, BLS-7-45, BLS-6-45**May 22, 2007  
99 days to decisionK070396 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k070396/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Feb 12, 2007
Decision date	May 22, 2007
Days to decision	99 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/k070396/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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