

**K080500 MODIFICATION TO: ACUMEN SINGLE-LUMEN
DELIVERY SHEATH, MODELS BLS-10, BLS-9, BLS-7**Mar 13, 2008
17 days to decisionK080500 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k080500/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Feb 25, 2008
Decision date	Mar 13, 2008
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acumen Medical, Inc.
Location	Mountain View, CA, US
Contact	KEVIN MACDONALD
510(k) history	12 submissions · 12 cleared · 2004-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080500/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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