

K053400 ACUMEN SINGLE-LUMEN DELIVERY SHEATHJun 19, 2006
195 days to decisionK053400 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k053400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 6, 2005
Decision date	Jun 19, 2006
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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