FDA 510(k) Premarket Notification

K070396 MODIFICATION TO: ACUMEN SINGLE-LUMEN DELIVERY SHEATH, MODELS BLS-8-45, BLS-7-45, BLS-6-45

CLEARED

May 22, 2007
99 days to decision

K070396 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k070396/

SUBMISSION DETAILS

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

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