FDA 510(k) Premarket Notification

K080500 MODIFICATION TO: ACUMEN SINGLE-LUMEN DELIVERY SHEATH, MODELS BLS-10, BLS-9, BLS-7

CLEARED

Mar 13, 2008
17 days to decision

K080500 · 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