

K042376 ACUMEN SHEATH, MODEL TTW7807Oct 26, 2004
55 days to decisionK042376 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k042376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 1, 2004
Decision date	Oct 26, 2004
Days to decision	55 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042376/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026