

K041506 INTRAVASCULAR ACCESS INTRODUCER SHEATHOct 15, 2004
130 days to decisionK041506 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k041506/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jun 7, 2004
Decision date	Oct 15, 2004
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Applied Medical Resources Corp.
Location	Rancho Santa, CA, US
Contact	CHERYL BLAKE
510(k) history	45 submissions · 45 cleared · 2001-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041506/> 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 May 26, 2026