

K004025 SPLITTABLE SHEATH INTRODUCER KITJul 19, 2001
204 days to decisionK004025 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k004025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Dec 27, 2000
Decision date	Jul 19, 2001
Days to decision	204 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Thomas Medical Products, Inc.
Location	Malvern, PA, US
Contact	KIMBERLY A FISCHER
510(k) history	23 submissions · 23 cleared · 1990-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k004025/> 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 9, 2026