

K120617 PTFE SUPER SHEATH INTRODUCERNov 19, 2012
264 days to decisionK120617 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k120617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 29, 2012
Decision date	Nov 19, 2012
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Martech Medical Products
Location	Harleysville, PA, US
Contact	ALEXIS ERAZO
510(k) history	3 submissions · 3 cleared · 2010-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120617/> 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 8, 2026