

K043084 PREMIERE DELIVERY SHEATH, MODEL PDSMay 2, 2005
175 days to decisionK043084 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k043084/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 8, 2004
Decision date	May 2, 2005
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Velocimed, Inc.
Location	Minneapolis, MN, US
Contact	JOHN CARLINE
510(k) history	5 submissions · 5 cleared · 2004-2006

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