

**K130687 2F & 3F VASCU-SHEATH TEARAWAY INTRODUCER**Aug 15, 2013  
155 days to decisionK130687 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k130687/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 13, 2013
Decision date	Aug 15, 2013
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medical Components, Inc.</b>
Location	Mchenry, IL, US
Contact	JESSICA LEO
510(k) history	63 submissions · 55 cleared · 1980-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130687/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026