

**K111943 AGILLS PF DELIVERY SYSTEM**Sep 29, 2011  
83 days to decisionK111943 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k111943/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 8, 2011
Decision date	Sep 29, 2011
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>St. Jude Medical, Cardiac Rhythm Management Divisi</b>
Location	Sylmar, CA, US
Contact	GEENA GEORGE
510(k) history	10 submissions · 10 cleared · 2008-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111943/> 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 June 15, 2026