

**K111417 THE POWERWAND (R) SAFETY INTRODUCER WITH AN EXTENDED DWELL CATHETER**Jul 15, 2011  
56 days to decisionK111417 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k111417/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	May 20, 2011
Decision date	Jul 15, 2011
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Access Scientific, Inc.</b>
Location	San Diego, CA, US
Contact	ALBERT MISAJON
510(k) history	8 submissions · 8 cleared · 2008-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111417/>; 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 14, 2026