

**K090365 HANSEN MEDICAL ARTISAN S CONTROL CATHETER**May 7, 2009  
83 days to decisionK090365 · Product code: **DXX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k090365/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Special
Device classification	System, Catheter Control, Steerable (DXX)
Date received	Feb 13, 2009
Decision date	May 7, 2009
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hansen Medical, Inc.</b>
Location	Mountain View, CA, US
Contact	KATE WHITIN
510(k) history	14 submissions · 10 cleared · 2006-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090365/> 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 2, 2026