

**K100169 DURASPAN HEMODIALYSIS LONG-TERM CATHETER**Feb 18, 2010  
29 days to decisionK100169 · Product code: **MSD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k100169/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Special
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Jan 20, 2010
Decision date	Feb 18, 2010
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>R4 Vascular, Inc.</b>
Location	St. Paul, MN, US
Contact	LAURIE LEWANDOWSKI
510(k) history	7 submissions · 5 cleared · 2007-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100169/> 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 8, 2026