

**K063431 15.5 FR DECATHLON GOLD, FUNNEL TIPS, COATED  
HEMODIALYSIS CATHETER, DFC19SH24, DFC23SH28,  
DFC27SH32, DFC31SH36, DFC35SH40**Jan 29, 2007  
77 days to decisionK063431 · Product code: **MSD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k063431/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Nov 13, 2006
Decision date	Jan 29, 2007
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spire Biomedical, Inc.</b>
Location	Bedford, MA, US
Contact	SHEKHAR D NIMKAR
510(k) history	16 submissions · 12 cleared · 2002-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063431/> 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 25, 2026