

**K073093 DECATHLON GOLD TWIN LUMEN HEMODIALYSIS  
CATHETER WITH SEPARATED TIPS, MODELS DEC19SH24,  
DEC23SH28, DEC23SH32, DEC31SH36,**Jan 22, 2008  
82 days to decisionK073093 · Product code: **MSD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k073093/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Nov 1, 2007
Decision date	Jan 22, 2008
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spire Biomedical, Inc.</b>
Location	Bedford, MA, US
Contact	RAYMOND KELLY
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/k073093/> 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