

**K073092 DECATHLON TWIN LUMEN HEMODIALYSIS  
CATHETER WITH SEPARATED TIPS, MODELS DE19SH24,  
DE23SH28, DE27SH32, DE31SH36, DE35SH40,**Jan 29, 2008  
89 days to decisionK073092 · Product code: **MSD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k073092/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Nov 1, 2007
Decision date	Jan 29, 2008
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k073092/> 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