

**K032061 DECATHLON TWIN LUMEN HEMODIALYSIS WITH SEPARATED TIPS, MODELS DE19/24SH, DE23/28SH, DE27/32SH, DE 31/36SH, DE19/24NH**Dec 23, 2003  
173 days to decisionK032061 · Product code: **MSD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k032061/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Jul 3, 2003
Decision date	Dec 23, 2003
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032061/> 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