

**K042858 55CM 15.5FR DECATHLON TWIN LUMEN
HEMODIALYSIS CATHETER W/SEPARATED TIPS**Dec 3, 2004
49 days to decisionK042858 · Product code: **MSD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k042858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Oct 15, 2004
Decision date	Dec 3, 2004
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042858/> Data sourced from FDA 510(k) public records (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. - Generated June 25, 2026