

**K041559 55CM POURCHEZ RETRO SAFE TRAC TWIN LUMEN
HEMODIALYSIS CATHETER MODEL
#RS50SH55,RS50NH55,RE50SH55 & RE50NH55**Jul 30, 2004
50 days to decisionK041559 · Product code: **MSD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k041559/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Jun 10, 2004
Decision date	Jul 30, 2004
Days to decision	50 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

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