

K040509 ALTA LR FIXED TIP CHRONIC HEMODIALYSIS CATHETER, MODELS AL19NH24, AL23NH28, AL27NH32, AL31NH36, AL35NH40

Apr 19, 2004
52 days to decision

K040509 · Product code: **MSD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k040509/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Feb 27, 2004
Decision date	Apr 19, 2004
Days to decision	52 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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Device record: <https://www.510kdatabase.net/k040509/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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