

**K063441 15.5FR ALTA GOLD, COATED HEMODIALYSIS
CATHETER, MODEL ALC19SH24, ALC23SH28, ALC27SH32,
ALC31SH36, ALC35SH40, ALC50SH55**Feb 12, 2007
90 days to decisionK063441 · Product code: **MSD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k063441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Nov 14, 2006
Decision date	Feb 12, 2007
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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