

**K062435 REPAIR KIT FOR XPRESSO, DECATHLON, AND ALTA
LR CATHETERS**Dec 5, 2006
106 days to decisionK062435 · Product code: **NFK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k062435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Repair, Catheter, Hemodialysis (NFK)
Date received	Aug 21, 2006
Decision date	Dec 5, 2006
Days to decision	106 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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