

**K022644 RETRO REPAIR KIT, MODEL PRRK5**Nov 6, 2002  
90 days to decisionK022644 · Product code: **NFK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k022644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Kit, Repair, Catheter, Hemodialysis (NFK)
Date received	Aug 8, 2002
Decision date	Nov 6, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k022644/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 25, 2026