

**K022620 SHEATHLESS ACCESSORY KIT, MODELS XRIK24,
XRIK28, XRIK32, XRIK36, XRIK40 AND XRIKRT**Oct 11, 2002
65 days to decisionK022620 · Product code: **FKA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k022620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel (FKA)
Date received	Aug 7, 2002
Decision date	Oct 11, 2002
Days to decision	65 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k022620/> Data sourced from FDA 510(k) public records (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. - Generated June 26, 2026