

K950247 TS 564/PFNov 17, 1995
301 days to decisionK950247 · Product code: **FJK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k950247/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Tubing, Blood, With And Without Anti-regurgitation Valve (FJK)
Date received	Jan 20, 1995
Decision date	Nov 17, 1995
Days to decision	301 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bressler, Amery & Ross
Location	Morristown, NJ, US
Contact	ERIC J NEMETH
510(k) history	1 submissions · 1 cleared · 1995-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950247/> 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 30, 2026