

**K012242 FRESENIUS ARTERIAL BLOODLINE SETS FOR
HEMODIALYSIS, FRESENIUS COMBI SETS HEMODIALYSIS
BLOOD TUBING SETS**Aug 16, 2001
30 days to decisionK012242 · Product code: **FJK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k012242/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Tubing, Blood, With And Without Anti-regurgitation Valve (FJK)
Date received	Jul 17, 2001
Decision date	Aug 16, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care North America
Location	Lexington, MA, US
Contact	ARTHUR EILINSFELD
510(k) history	43 submissions · 43 cleared · 1998-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012242/> 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 28, 2026