

K252423 NovaLine Tubing Set for Hemodialysis (BL 124)May 15, 2026
287 days to decisionK252423 · Product code: **FJK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k252423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Tubing, Blood, With And Without Anti-regurgitation Valve (FJK)
Date received	Aug 1, 2025
Decision date	May 15, 2026
Days to decision	287 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bain Medical Equipment (Guangzhou) Co., Ltd.
Location	Guangzhou, CN
Contact	Zoe Zeng
510(k) history	7 submissions · 7 cleared · 2017-2026

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