

**K161582 DORA Tubing Sets for Hemodialysis**Jun 16, 2017  
373 days to decisionK161582 · Product code: **FJK** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k161582/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Tubing, Blood, With And Without Anti-regurgitation Valve (FJK)
Date received	Jun 8, 2016
Decision date	Jun 16, 2017
Days to decision	373 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bain Medical Equipment (Guangzhou) Co., Ltd.</b>
Location	Guangzhou, CN
Contact	Sophia Shao
510(k) history	6 submissions · 6 cleared · 2017-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161582/> 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 May 26, 2026