

K163025 DORA Disposable A.V. Fistula Needle SetsJul 20, 2017
262 days to decisionK163025 · Product code: **FIE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k163025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Oct 31, 2016
Decision date	Jul 20, 2017
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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