

K213015 DORA Disposable A.V. Fistula Needle SetsApr 8, 2022
200 days to decisionK213015 · Product code: **FIE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k213015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Sep 20, 2021
Decision date	Apr 8, 2022
Days to decision	200 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	6 submissions · 6 cleared · 2017-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213015/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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