

K230925 Disposable Injection Needle AF seriesSep 27, 2023
177 days to decisionK230925 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k230925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Apr 3, 2023
Decision date	Sep 27, 2023
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alton (Shanghai) Medical Instruments Co., Ltd.
Location	Shanghai, CN
Contact	Vivian Li
510(k) history	6 submissions · 6 cleared · 2023-2025

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