

K232200 Disposable Injection NeedlesApr 12, 2024
262 days to decisionK232200 · Product code: **FBK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k232200/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Jul 25, 2023
Decision date	Apr 12, 2024
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo Xinwell Medical Technology Co., Ltd.
Location	Ningbo Cixi, CN
Contact	Lei Xi
510(k) history	2 submissions · 2 cleared · 2024-2024

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