

K210917 Single Use Injection NeedleMay 28, 2021
60 days to decisionK210917 · Product code: **FBK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k210917/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Mar 29, 2021
Decision date	May 28, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anrei Medical (Hangzhou) Co., Ltd.
Location	Hangzhou, CN
Contact	Huiping Yang
510(k) history	6 submissions · 6 cleared · 2020-2022

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