

K213914 Injection NeedleJul 29, 2022
226 days to decisionK213914 · Product code: **FBK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k213914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Dec 15, 2021
Decision date	Jul 29, 2022
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Vedkang Medical Science and Technology Co., Ltd.
Location	Changzhou, CN
Contact	Ting Tang
510(k) history	7 submissions · 7 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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