

**K220292 Disposable Endoscope Injection Needle**Aug 19, 2022  
199 days to decisionK220292 · Product code: **FBK** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k220292/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Feb 1, 2022
Decision date	Aug 19, 2022
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Yangzhou Fartley Medical Instrument Technology Co., Ltd.</b>
Location	Yangzhou, CN
Contact	Tina Han
510(k) history	7 submissions · 7 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Thinkwell Consulting Co., Ltd.</b>
Contact	Ethan Liu

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

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