

**K213239 Endoscopic Injection Needle**Jun 2, 2022  
245 days to decisionK213239 · Product code: **FBK** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k213239/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Sep 30, 2021
Decision date	Jun 2, 2022
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beijing Zksk Technology Co., Ltd.</b>
Location	Beijing, CN
Contact	Ma Li
510(k) history	6 submissions · 6 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
Contact	Boyle Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213239/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 24, 2026