

**K240675 Endoscopic Injection Needles**Oct 4, 2024  
207 days to decisionK240675 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k240675/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Mar 11, 2024
Decision date	Oct 4, 2024
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Promised Hangzhou Meditech Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Yang Zearou
510(k) history	34 submissions · 34 cleared · 2017-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240675/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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