

**K232442 Disposable Endoscope Injection Needles**Nov 9, 2023  
87 days to decisionK232442 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k232442/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Aug 14, 2023
Decision date	Nov 9, 2023
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhejiang Soudon Medical Technology Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Junshi Wang
510(k) history	4 submissions · 4 cleared · 2023-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232442/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026