

**K221054 CORE-INJECTOR**Dec 21, 2022  
254 days to decisionK221054 · Product code: **FBK** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k221054/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Apr 11, 2022
Decision date	Dec 21, 2022
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Incore Co., Ltd.</b>
Location	Daegu, KR
Contact	Jae-Hun Lee
510(k) history	6 submissions · 6 cleared · 2022-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221054/> 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 24, 2026