

**K223327 Sterile Aesthetic Cannula and Hypodermic Needle**Feb 16, 2023  
108 days to decisionK223327 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k223327/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 31, 2022
Decision date	Feb 16, 2023
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai Kindly Enterprise Development Group Co., Ltd.</b>
Location	Shanghai, CN
Contact	Liu Hualong
510(k) history	2 submissions · 2 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Mind-Link Consulting Co., Ltd.</b>
Contact	Evan Hu

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/k223327/> 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 27, 2026