

**K214075 Safety Blood Collection / Infusion Set (with/without needle holder), Blood Collection / Infusion Set (with/without needle holder)**Apr 12, 2022  
106 days to decisionK214075 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k214075/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 27, 2021
Decision date	Apr 12, 2022
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.</b>
Location	Taihu, Anqing City, CN
Contact	Bingyi Xiang
510(k) history	12 submissions · 12 cleared · 2019-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Irc</b>
Contact	Charles Mack

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/k214075/>. 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 26, 2026