

**K222124 Sterile Hypodermic Syringe with/without Needle,
Hypodermic Needle**Nov 4, 2022
109 days to decisionK222124 · Product code: FMI · General Hospital
Source: <https://www.510kdatabase.net/k222124/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 18, 2022
Decision date	Nov 4, 2022
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Irc
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.netDevice record: <https://www.510kdatabase.net/k222124/>; Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026