

**K212857 Sterile Syringe for Single Use (with Needle), Sterile Hypodermic Needle for Single Use**May 9, 2023  
608 days to decisionK212857 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k212857/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 8, 2021
Decision date	May 9, 2023
Days to decision	608 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Zhiyu Medical Instrument Co, Ltd.</b>
Location	Taixing, CN
Contact	Lianhua Cao
510(k) history	1 submissions · 1 cleared · 2023-2023

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212857/>. 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