

**K212846 Sterile Hypodermic Syringe for Single Use,
with/without Needle, Sterile Hypodermic Needle for Single Use**Aug 30, 2022
357 days to decisionK212846 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k212846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 7, 2021
Decision date	Aug 30, 2022
Days to decision	357 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Jichun Medical Devices Co., Ltd.
Location	Changzhou, CN
Contact	Zhu Pingnan
510(k) history	1 submissions · 1 cleared · 2022-2022

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/k212846/> 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