

K221068 Sterile Hypodermic Syringes for Single Use with NeedlesOct 4, 2022
175 days to decisionK221068 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k221068/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 12, 2022
Decision date	Oct 4, 2022
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sichuan Prius Biotechnology Co., Ltd.
Location	Yibin, CN
Contact	Yan Liu
510(k) history	9 submissions · 9 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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/k221068/> 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