

**K212920 Sterile Safety Syringe with Needle for Single Use,  
Sterile Safety Hypodermic Needle for Single Use, Sterile Auto-  
Disable Syringe with Needle for Single Use**Mar 11, 2022  
178 days to decisionK212920 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k212920/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 14, 2021
Decision date	Mar 11, 2022
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shandong Weigao Group Medical Polymer Co., Ltd.</b>
Location	Shanghai, CN
Contact	Lina Liu
510(k) history	7 submissions · 7 cleared · 2007-2023

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212920/> 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