

K211211 Sterile syringes for single use with/without needleOct 7, 2021
167 days to decisionK211211 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k211211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 23, 2021
Decision date	Oct 7, 2021
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Azur Medical Company, Inc.
Location	Richmond, VA, US
Contact	Di Zhao
510(k) history	4 submissions · 4 cleared · 2021-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211211/> 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