

K211214 Sterile Hypodermic Needles for Single UseOct 14, 2021
174 days to decisionK211214 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k211214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 23, 2021
Decision date	Oct 14, 2021
Days to decision	174 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/k211214/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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