

K212677 aboNT SYRINGEApr 15, 2022
234 days to decisionK212677 · Product code: **FMF** · General HospitalSource: <https://www.510kdatabase.net/k212677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Aug 24, 2021
Decision date	Apr 15, 2022
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nipro Medical Corporation
Location	Lexington, KY, US
Contact	Jessica Oswald-McLeod
510(k) history	34 submissions · 34 cleared · 2005-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212677/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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