FDA 510(k) Premarket Notification

K212677 aboNT SYRINGE

CLEARED

Apr 15, 2022
234 days to decision

K212677 · Product code: **FMF** · General Hospital
Source: 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