

K253047 PRESSONE™Mar 24, 2026
183 days to decisionK253047 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k253047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 22, 2025
Decision date	Mar 24, 2026
Days to decision	183 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

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