FDA 510(k) Premarket Notification

# K253047 PRESSONE™

**CLEARED**

Mar 24, 2026
183 days to decision

K253047 · Product code: **FMI** · General Hospital
Source: 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 |