

K252015 FreedomEdge Infusion SystemJan 28, 2026
215 days to decisionK252015 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k252015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jun 27, 2025
Decision date	Jan 28, 2026
Days to decision	215 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	High-Flo SubQ Needle Set; Precision Flow Rate Tubing

APPLICANT

Company	Koru Medical Systems, Inc.
Location	Mahwah, NJ, US
Contact	Emily DiMambro
Website	http://www.rmsmedicalproducts.com/
510(k) history	1 submissions · 1 cleared · 2026-2026

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