

K231918 Freedom60 Infusion PumpNov 3, 2023
127 days to decisionK231918 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k231918/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jun 29, 2023
Decision date	Nov 3, 2023
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	High-Flo Subcutaneous Needle Sets; Precision Flow Rate Tubing; High-Flo Super26 Subcutaneous Needle Sets; Freedom60 Pre-Filled Syringe Adapter

APPLICANT

Company	Koru Medical Systems
Location	Mahwah, NJ, US
Contact	Emily DiMambro
Website	http://www.rmsmedicalproducts.com/
510(k) history	1 submissions · 1 cleared · 2023-2023

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