

K214045 FreedomEdge Syringe Infusion SystemApr 29, 2022
123 days to decisionK214045 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k214045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Dec 27, 2021
Decision date	Apr 29, 2022
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Repro-Medical System, Inc., Db a Koru Medical Systems
Location	New York, NY, US
Contact	Christopher Pazdan
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	510K Technology Group, LLC
Contact	Kachi Enyinna

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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