

**K250357 RemunityPRO™ Pump for Remodulin® (treprostinil)
Injection**Mar 11, 2025
32 days to decisionK250357 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k250357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion (FRN)
Date received	Feb 7, 2025
Decision date	Mar 11, 2025
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Deka Research & Development Corp.
Location	Mchenry, IL, US
Contact	Paul Smolenski
510(k) history	10 submissions · 10 cleared · 1984-2025

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