

K253703 RemunityPRO+ Pump for Remodulin® (treprostinil) Injection

Jul 24, 2026
242 days to decision

K253703 · Product code: FRN · General Hospital
Source: <https://www.510kdatabase.net/k253703/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Nov 24, 2025
Decision date	Jul 24, 2026
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Deka R&D Corp
Location	Manchester, NH, US
Contact	Paul Smolenski
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k253703/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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