FDA 510(k) Premarket Notification

K243786 Bicarby Dialysate RFP-402 (RFP-402-G)

CLEARED

Apr 4, 2025
116 days to decision

K243786 · Product code: **KPO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k243786/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Dec 9, 2024
Decision date	Apr 4, 2025
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Bicarby Dialysate RFP-400 (RFP-400-G); Bicarby Dialysate RFP-407 (RFP-407-G); Bicarby Dialysate RFP-401 (RFP-401-G); Bicarby Dialysate RFP-404 (RFP-404-G); Bicarby Dialysate RFP-456 (RFP-456-G); Ci-Ca Dialysate 2K (RFP-457-G); Ci-Ca Dialysate 4K (RFP-458-G)

APPLICANT

Company	**Fresenius Medical Care Renal Therapies Group, LLC**
Location	Waltham, MA, US
Contact	Timothy Groves
Website	https://www.freseniusmedicalcare.com
510(k) history	50 submissions · 50 cleared · 2013-2026

Fresenius Medical Care Renal Therapies Group, LLC is a medical device manufacturer based in Waltham, US. The company specializes in renal therapy and dialysis technologies. The company has received FDA 510(k) clearances from total submissions since 2013. 96% of submissions focus on Gastroenterology & Urology devices, reflecting the company's core expertise in dialysis and renal replacement therapies. The latest clearance was in 2026, confirming active regulatory engagement. Recent cleared devices include hemodialysis systems, dialyzers, body composition monitors, and dial...