

**K252180 Bicarby Dialysate RFP-404 (RFP-404-W)**

Sep 9, 2025  
60 days to decision

K252180 · Product code: **KPO** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k252180/>

**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Jul 11, 2025
Decision date	Sep 9, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Bicarby Dialysate RFP-403 (RFP-403-W); Bicarby Dialysate RFP-403 (RFP-403-G); Bicarby Dialysate RFP-453 (RFP-453-W); Bicarby Dialysate RFP-453 (RFP-453-G); Bicarby Dialysate RFP-454 (RFP-454-W); Bicarby Dialysate RFP-454 (RFP-454-G); Bicarby Dialysate RFP-456 (RFP-456-W)

**APPLICANT**

Company	<b>Fresenius Medical Care Renal Therapies Group, LLC</b>
Location	Waltham, MA, US
Contact	Timothy Groves
Website	<a href="https://www.freseniusmedicalcare.com">https://www.freseniusmedicalcare.com</a>
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...