

**K162716 bibag**May 18, 2017  
231 days to decisionK162716 · Product code: **KPO** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k162716/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Sep 29, 2016
Decision date	May 18, 2017
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fresenius Medical Care Renal Therapies Group, LLC</b>
Location	Waltham, MA, US
Contact	Denise Oppermann
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...

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