

K253518 FX CorAL 40Dec 18, 2025
36 days to decisionK253518 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k253518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 12, 2025
Decision date	Dec 18, 2025
Days to decision	36 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FX CorAL 50

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...

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