

K153449 2008K2 Hemodialysis MachineApr 26, 2016
148 days to decisionK153449 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k153449/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 30, 2015
Decision date	Apr 26, 2016
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care Renal Therapies Group, LLC
Location	Waltham, MA, US
Contact	DENISE OPPERMANN
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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