

K252459 multiFlux 130 (F00013123)Feb 10, 2026
189 days to decisionK252459 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 5, 2025
Decision date	Feb 10, 2026
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	multiFlux 160 (F00013124)

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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252459/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026