

K261267 Careflux H60

Jul 24, 2026
99 days to decision

K261267 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k261267/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 16, 2026
Decision date	Jul 24, 2026
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Careflux H70;Careflux V500

APPLICANT

Company	Fresenius Medical Care Renal Therapies Group, LLC
Location	Waltham, MA, US
Contact	Timothy Groves
Website	https://www.freseniusmedicalcare.com
510(k) history	52 submissions · 52 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...