FDA 510(k) Premarket Notification

K233950 pureFLOW 402 (F00012067)

CLEARED

May 10, 2024
148 days to decision

K233950 · Product code: **KPO** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k233950/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Dec 14, 2023
Decision date	May 10, 2024
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	pureFLOW 406 (F00012068); pureFLOW 401 (F00012069); pureFLOW 400 (F00012070)

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...