

K231534 5008X Hemodialysis SystemFeb 2, 2024
248 days to decisionK231534 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k231534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 30, 2023
Decision date	Feb 2, 2024
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care
Location	Lexington, MA, US
Contact	Denise M Oppermann
Website	http://www.fmc-ag.com/
510(k) history	7 submissions · 7 cleared · 2000-2024

Fresenius Medical Care is a global provider of dialysis products and services. The company operates with a manufacturing facility in Lexington, US. It specializes in Gastroenterology & Urology devices for kidney replacement therapy and renal care. The company has received FDA 510(k) clearances from total submissions. All submissions focus on Gastroenterology & Urology devices. Fresenius Medical Care's regulatory activity spans from 2000 to 2024, with its most recent clearance in 2024, demonstrating continued innovation in renal care technologies. The company's cleared dev...