

**K030497 FRESENIUS NATURALYTE GRANUFLO DRY ACID
CONCENTRATE 10XX SERIES, 24XX SERIES, 30XX SERIES**May 20, 2003
90 days to decisionK030497 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k030497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Feb 19, 2003
Decision date	May 20, 2003
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care
Location	Lexington, MA, US
Contact	ART EILINSFELD
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...

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