

K034064 FRESENIUS ULTRAFLO HPX HEMODIALYZERJan 30, 2004
30 days to decisionK034064 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k034064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 31, 2003
Decision date	Jan 30, 2004
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care North America
Location	Lexington, MA, US
Contact	ARTHUR EILINSFELD
510(k) history	43 submissions · 43 cleared · 1998-2025

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