

K031378 FRESENIUS ULTRAFLUX HEMODIALYZERMay 30, 2003
29 days to decisionK031378 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k031378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 1, 2003
Decision date	May 30, 2003
Days to decision	29 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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