

K043244 FRESENIUS OPTIFLUX F20NR, FF18NR, F16NRDec 20, 2004
27 days to decisionK043244 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k043244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 23, 2004
Decision date	Dec 20, 2004
Days to decision	27 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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