

K003498 FRESENIUS OPTIFLUX 200AJan 4, 2001
52 days to decisionK003498 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k003498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 13, 2000
Decision date	Jan 4, 2001
Days to decision	52 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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