

**K002277 FRESENIUS OPTIFLUX 200NR**Aug 25, 2000  
30 days to decisionK002277 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k002277/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 26, 2000
Decision date	Aug 25, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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