

**K082414 OPTIFLUX F250NR, MODEL 0500325E**Oct 28, 2008  
68 days to decisionK082414 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k082414/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 21, 2008
Decision date	Oct 28, 2008
Days to decision	68 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	JANET KAY
510(k) history	43 submissions · 43 cleared · 1998-2025

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