

K123262 OPTIFLUX ULTRA DIALYZERJan 6, 2014
445 days to decisionK123262 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k123262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 18, 2012
Decision date	Jan 6, 2014
Days to decision	445 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care North America
Location	Lexington, MA, US
Contact	DENISE OPPERMANN
510(k) history	43 submissions · 43 cleared · 1998-2025

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