

K152367 Optiflux dialyzerOct 29, 2015
69 days to decisionK152367 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k152367/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 21, 2015
Decision date	Oct 29, 2015
Days to decision	69 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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