

K162488 Optiflux dialyzerApr 6, 2017
211 days to decisionK162488 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k162488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Sep 7, 2016
Decision date	Apr 6, 2017
Days to decision	211 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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