

**K192928 Optiflux Enexa F500 Dialyzer**Jul 9, 2020  
266 days to decisionK192928 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k192928/>**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	Oct 17, 2019
Decision date	Jul 9, 2020
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fresenius Medical Care Renal Therapies Group, LLC</b>
Location	Waltham, MA, US
Contact	Denise Oppermann
510(k) history	1 submissions · 1 cleared · 2020-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192928/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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