FDA 510(k) Premarket Notification

K192928 Optiflux Enexa F500 Dialyzer

CLEARED

Jul 9, 2020
266 days to decision

K192928 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k192928/

SUBMISSION DETAILS

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

Company	**Fresenius Medical Care Reanal Therapies Group, LLC**
Location	Waltham, MA, US
Contact	Denise Oppermann
510(k) history	1 submissions · 1 cleared · 2020-2020