

K210575 HDF Assist Mudule, HDF Infusion Set and Substitution FilterMay 13, 2022
441 days to decisionK210575 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k210575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 26, 2021
Decision date	May 13, 2022
Days to decision	441 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nephros
Location	South Orange, NJ, US
Contact	Vashone R Thomas
510(k) history	1 submissions · 1 cleared · 2022-2022

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