

K221652 NIKKICARTMar 3, 2023
269 days to decisionK221652 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k221652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Jun 7, 2022
Decision date	Mar 3, 2023
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Renal Care Dialysis Solutions, S.A. DE C.V.
Location	El Marques, MX
Contact	Jose Enrique Aguirre Valades
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Namsa
Contact	Brittany Valdez Nava

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221652/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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