

K233213 NxStage PureFlow SolutionJan 18, 2024
112 days to decisionK233213 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k233213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Sep 28, 2023
Decision date	Jan 18, 2024
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nxstage Medical, Inc.
Location	Tewksburt, MA, US
Contact	Caitlin Kalda
510(k) history	51 submissions · 51 cleared · 2001-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233213/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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