

K212052 HMB32 Dialysis SolutionJul 23, 2021
23 days to decisionK212052 · Product code: **KPO** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k212052/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Jun 30, 2021
Decision date	Jul 23, 2021
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Haemopharm Biofluids S.R.L.
Location	Tovo Di S. Agata, IT
Contact	Francesca Curti
510(k) history	2 submissions · 2 cleared · 2015-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212052/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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