

**K240920 HemoCare Bicarbonate Concentrate Set (BCS)**Jul 12, 2024  
99 days to decisionK240920 · Product code: **KPO** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k240920/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Apr 4, 2024
Decision date	Jul 12, 2024
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Deka Research and Development</b>
Location	Manchester, NH, US
Contact	Paul Smolenski
510(k) history	11 submissions · 11 cleared · 2015-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240920/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026