

**K243920 Purema H Hemoconcentrator - Pediatric**Sep 19, 2025  
273 days to decisionK243920 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k243920/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 20, 2024
Decision date	Sep 19, 2025
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medica USA, Inc.</b>
Location	Minnetonka, MN, US
Contact	Greg Collins
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Amarex Clinical Research, LLC</b>
Contact	Ahmad Bayat

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243920/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026