

K233557 HemoCare Hemodialysis SystemJul 12, 2024
249 days to decisionK233557 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k233557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 6, 2023
Decision date	Jul 12, 2024
Days to decision	249 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233557/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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