

K232467 CleanCart A, CleanCart C, AK 98 Hemodialysis MachineSep 14, 2023
30 days to decisionK232467 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k232467/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Aug 15, 2023
Decision date	Sep 14, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Healthcare Corporation
Location	Round Lake, IL, US
Contact	Kristen Bozzelli
510(k) history	61 submissions · 60 cleared · 2004-2025

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