

**K201809 AK 98 Dialysis Machine, U9000 Ultrafilter, C705
Expansion Chamber Accessory**Mar 10, 2021
252 days to decisionK201809 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k201809/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 1, 2020
Decision date	Mar 10, 2021
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Healthcare Corporation
Location	Round Lake, IL, US
Contact	Kristen Bozzelli
510(k) history	3 submissions · 3 cleared · 2020-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201809/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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