

**K974652 BLOOD MONITOR PUMP WITH ULTRAFILTRATION
CONTROLLER**Jul 10, 1998
210 days to decisionK974652 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k974652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 12, 1997
Decision date	Jul 10, 1998
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Healthcare Corp
Location	Mchenry, IL, US
Contact	DAVID E CURTIN
510(k) history	505 submissions · 496 cleared · 1977-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974652/> Data sourced from FDA 510(k) public records (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. - Generated May 17, 2026