

**K090002 ACID CONCENTRATE 45X (2.0K, 3.1CA), MODEL
5M8001A, ACID CONCENTRATE 45X (2.0K, 2.5CA), MODEL
5M8002A**Aug 7, 2009
217 days to decisionK090002 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k090002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Jan 2, 2009
Decision date	Aug 7, 2009
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090002/> 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