

**K023985 ACIDIFIED COMPONENT CONCENTRATES FOR
BICARBONATE DIALYSIS CONTAINING DI-ACETATE**Feb 28, 2003
88 days to decisionK023985 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k023985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Dec 2, 2002
Decision date	Feb 28, 2003
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rockwell Medical Technologies, Inc.
Location	Wixom, MI, US
Contact	GERRY FRITZ
510(k) history	5 submissions · 5 cleared · 1999-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k023985/> 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 June 29, 2026