

**K011368 DRY AC ACID CONCENTRATE MIX FOR
BICARBONATE HEMODIALYSIS**Aug 2, 2001
90 days to decisionK011368 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	May 4, 2001
Decision date	Aug 2, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gambro Renal Products
Location	Lakewood, CO, US
Contact	FEI LAW
510(k) history	24 submissions · 23 cleared · 2000-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011368/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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