

**K052253 MODIFICATION TO: DRYAC ACID CONCENTRATE MIX
FOR BICARBONATE HEMODIALYSIS**Nov 2, 2005
76 days to decisionK052253 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k052253/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Aug 18, 2005
Decision date	Nov 2, 2005
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

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/k052253/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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