

**K010985 GAMBRO POLYFLUX 6L, GAMBRO POLYFLUX 8L,
GAMBRO POLYFLUX 10L, MODEL 6L, 8L, 10L**Oct 10, 2001
191 days to decisionK010985 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k010985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 2, 2001
Decision date	Oct 10, 2001
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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