

**K010667 GAMBRO POLYFLUX 24S, GAMBRO POLYFLUX 24R**Jun 4, 2001  
90 days to decisionK010667 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k010667/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 6, 2001
Decision date	Jun 4, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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