

**K982414 GAMBRO POLYFLUX 11S, 14S, 17S & 21S
HEMODIALYZERS/ HEMOFILTERS**Mar 26, 1999
256 days to decisionK982414 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k982414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 13, 1998
Decision date	Mar 26, 1999
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro Healthcare
Location	Oklahoma City, OK, US
Contact	JEFFREY R SHIDEMAN
510(k) history	13 submissions · 13 cleared · 1996-2000

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