

K955487 GAMBRO POLYFLUX 14, 17, & 21 HEMODIALYZERSApr 18, 1997
504 days to decisionK955487 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k955487/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 1, 1995
Decision date	Apr 18, 1997
Days to decision	504 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cobe Renal Care, Inc.
Location	Lakewood, CO, US
Contact	JEFFREY R SHIDEMAN
510(k) history	14 submissions · 14 cleared · 1994-1997

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