

K042938 GAMBRO PRISMAFLEX HF1000 AND HF1400 SETSJan 6, 2005
73 days to decisionK042938 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k042938/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 25, 2004
Decision date	Jan 6, 2005
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro Renal Products
Location	Lakewood, CO, US
Contact	THOMAS B DOWELL
510(k) history	24 submissions · 23 cleared · 2000-2012

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