

K011221 PRISMA HF 1000 SET, PRISMA HF 1000 PRE-SETOct 31, 2001
194 days to decisionK011221 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k011221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 20, 2001
Decision date	Oct 31, 2001
Days to decision	194 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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