

K131516 PRISMAFLEX SYSTEM 7.10Jan 3, 2014
220 days to decisionK131516 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k131516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 28, 2013
Decision date	Jan 3, 2014
Days to decision	220 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gambro Renal Products, Inc.
Location	Lakewood, CO, US
Contact	KAE MILLER
510(k) history	13 submissions · 13 cleared · 2004-2014

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