

K063183 PRISMA M10 PRE SETFeb 15, 2007
119 days to decisionK063183 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k063183/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 19, 2006
Decision date	Feb 15, 2007
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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