

K062090 PRISMA SYSTEM R03.10AOct 18, 2006
86 days to decisionK062090 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k062090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 24, 2006
Decision date	Oct 18, 2006
Days to decision	86 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062090/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 14, 2026