

**K010805 PRISMA SYSTEM**Aug 6, 2002  
508 days to decisionK010805 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k010805/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 16, 2001
Decision date	Aug 6, 2002
Days to decision	508 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010805/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 14, 2026