

**K041005 GAMBRO PRISMAFLEX AND GAMBRO PRISMAFLEX  
M60 & M100 SETS**Oct 7, 2004  
171 days to decisionK041005 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k041005/>**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	Apr 19, 2004
Decision date	Oct 7, 2004
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gambro Renal Products</b>
Location	Lakewood, CO, US
Contact	THOMAS B DOWELL
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/k041005/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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