

**K060195 GAMBRO POLYFLUX HD-C4 CAPILLARY  
DIALYZER/FILTER FOR SINGLE USE**Apr 24, 2006  
89 days to decisionK060195 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k060195/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jan 25, 2006
Decision date	Apr 24, 2006
Days to decision	89 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/k060195/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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