

**K051520 GAMBRO POLYFLUX HEMODIALYZER, MODEL 6H**Dec 9, 2005  
184 days to decisionK051520 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k051520/>**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	Jun 8, 2005
Decision date	Dec 9, 2005
Days to decision	184 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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