

K072093 PRISMAFLEX SYSTEM, VERSION 3.20Feb 1, 2008
186 days to decisionK072093 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k072093/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jul 30, 2007
Decision date	Feb 1, 2008
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro
Location	Lakewood, CO, US
Contact	THOMAS B DOWELL
Website	http://www.gambro.com/en/global/
510(k) history	1 submissions · 1 cleared · 2008-2008

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