

**K040255 POLYFLUX 14L, 17L, 21L HEMODIALYZER/FILTER
LABELED FOR SINGLE USE**May 24, 2004
110 days to decisionK040255 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k040255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 4, 2004
Decision date	May 24, 2004
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro Renal Products, Inc.
Location	Lakewood, CO, US
Contact	JEAN WILLEY
510(k) history	13 submissions · 13 cleared · 2004-2014

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