

**K043342 POLYFLUX FAMILY HEMODIALYZER/FILTER
LABELED FOR SINGLE AND MULTIPLE USE, MODELS 14L,
17L, 21L, 140H, 170H, 210H,6LR, 8LR**May 27, 2005
172 days to decisionK043342 · Product code: **FJI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k043342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Dec 6, 2004
Decision date	May 27, 2005
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gambro Renal Products
Location	Lakewood, CO, US
Contact	KAE MILLER
510(k) history	24 submissions · 23 cleared · 2000-2012

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