

**K100364 GAMBRO CARTRIDGE BLOOD SET LOW WEIGHT-
LOW VOLUME, MODEL 003422-520**Nov 3, 2010
264 days to decisionK100364 · Product code: **FJK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k100364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Tubing, Blood, With And Without Anti-regurgitation Valve (FJK)
Date received	Feb 12, 2010
Decision date	Nov 3, 2010
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100364/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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