

K042797 WRO 300 WATER PURIFICATION SYSTEM FOR HEMODIALYSISMar 9, 2005
152 days to decisionK042797 · Product code: **FIP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k042797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Subsystem, Water Purification (FIP)
Date received	Oct 8, 2004
Decision date	Mar 9, 2005
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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