

**K864094 GAMBRO FLUID CONTROL MONITOR FCM 10-1**Nov 7, 1986  
17 days to decisionK864094 · Product code: **FKP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k864094/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Single Patient (FKP)
Date received	Oct 21, 1986
Decision date	Nov 7, 1986
Days to decision	17 days
Third-party review	No

**APPLICANT**

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Company	<b>Gambro, Inc.</b>
Location	Mchenry, IL, US
Contact	JEFFREY R SHIDEMAN
510(k) history	86 submissions · 86 cleared · 1976-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864094/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 23, 2026