

**K850621 GAMBRO PLASMAFILTRATION SYSTEM**May 16, 1985  
90 days to decisionK850621 · Product code: **LKN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k850621/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Feb 15, 1985
Decision date	May 16, 1985
Days to decision	90 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/k850621/>, 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