

**K915504 GAMBRO LUNDIA ALPHA HEMODIALYZERS**Mar 6, 1992  
88 days to decisionK915504 · Product code: **FJG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k915504/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Parallel Flow (FJG)
Date received	Dec 9, 1991
Decision date	Mar 6, 1992
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>C.G.H. Medical, Inc.</b>
Location	Lakewood, CO, US
Contact	VERA BUFFALOE
510(k) history	11 submissions · 11 cleared · 1991-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915504/> 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 26, 2026