

**K801480 GAMBRO LUNDIA MAJOR HIGH FLUX HEMODIALYZ**Aug 27, 1980  
64 days to decisionK801480 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k801480/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jun 24, 1980
Decision date	Aug 27, 1980
Days to decision	64 days
Third-party review	No

**APPLICANT**

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Company	<b>Gambro, Inc.</b>
Location	Mchenry, IL, US
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/k801480/> 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