

**K810066 COBE PPD .8**Jun 9, 1981  
147 days to decisionK810066 · Product code: **FJG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k810066/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Parallel Flow (FJG)
Date received	Jan 13, 1981
Decision date	Jun 9, 1981
Days to decision	147 days
Third-party review	No

**APPLICANT**

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Company	<b>Cobe Laboratories, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.gambro.com">https://www.gambro.com</a>
510(k) history	77 submissions · 77 cleared · 1976-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k810066/>; 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