

**K945746 GAMBRO LUNDIA 94-500 DIALYZER**Sep 8, 1995  
289 days to decisionK945746 · Product code: **FJI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k945746/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, Capillary, Hollow Fiber (FJI)
Date received	Nov 23, 1994
Decision date	Sep 8, 1995
Days to decision	289 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cobe Renal Care, Inc.</b>
Location	Lakewood, CO, US
Contact	JEFFREY R SHIDEMAN
510(k) history	14 submissions · 14 cleared · 1994-1997

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