

**K945747 GAMBRO LUNDIA 94-600 DIALYZER**Sep 8, 1995  
289 days to decisionK945747 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k945747/>**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	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 SHIEDMAN
510(k) history	14 submissions · 14 cleared · 1994-1997

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