

**K920757 FILTRAL HEMODIALYZERS**Aug 5, 1994  
898 days to decisionK920757 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k920757/>**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	Feb 19, 1992
Decision date	Aug 5, 1994
Days to decision	898 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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