

**K955497 GAMBRO FH 22H FIBER HEMOFLTR/PRISMA FH 22H
BLOOD TUBING/HEMOFLTR SET**Sep 25, 1997
664 days to decisionK955497 · Product code: **KDL** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Perfusion, Kidney, Disposable (KDL)
Date received	Dec 1, 1995
Decision date	Sep 25, 1997
Days to decision	664 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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