

K981085 GAMBRO HEMODIALYSIS WATER TREATMENT SYSTEMMay 18, 1998
54 days to decisionK981085 · Product code: **FIP** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Mar 25, 1998
Decision date	May 18, 1998
Days to decision	54 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gambro Healthcare
Location	Oklahoma City, OK, US
Contact	WILLIAM M TOWNSEND
510(k) history	13 submissions · 13 cleared · 1996-2000

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