

K970674 G.E.M. WATER SYSTEMS, INTERNATIONALNov 19, 1997
268 days to decisionK970674 · Product code: **FIN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970674/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tank, Holding, Dialysis (FIN)
Date received	Feb 24, 1997
Decision date	Nov 19, 1997
Days to decision	268 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	G.E.M. Water Systems
Location	Cypress, CA, US
Contact	JACK ENKOWITZ
510(k) history	3 submissions · 3 cleared · 1995-1997

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