

K944492 DIALYZER REPROCESSING SYSTEMAug 28, 1995
349 days to decisionK944492 · Product code: **LIF** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer Reprocessing System (LIF)
Date received	Sep 13, 1994
Decision date	Aug 28, 1995
Days to decision	349 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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