

K970650 ASAHI AM-R SERIES DIALYZERSSep 30, 1997
222 days to decisionK970650 · Product code: **MSE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialyzer, Re-use, Low Flux (MSE)
Date received	Feb 20, 1997
Decision date	Sep 30, 1997
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Asahi Medical Co., Ltd.
Location	Walker, MI, US
Contact	DAVID L WEST
510(k) history	16 submissions · 16 cleared · 1983-2004

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