

K983720 ASAHI AM-BIO SERIES DIALYZERS (WET MODELS)& (DRY MODELS), MODELS AM-BIO-50,AM-BIO-65, AM-BIO-75, AND AM-BIO-100, AM-BIO-

May 17, 1999
208 days to decision

K983720 · Product code: **MSE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k983720/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialyzer, Re-use, Low Flux (MSE)
Date received	Oct 21, 1998
Decision date	May 17, 1999
Days to decision	208 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k983720/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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