

**K013418 AM-BIO EXTENDED RANGE SERIES DIALYZER,
MODELS WET AND DRY**Jul 9, 2002
267 days to decisionK013418 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k013418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 15, 2001
Decision date	Jul 9, 2002
Days to decision	267 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.netDevice record: <https://www.510kdatabase.net/k013418/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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