FDA 510(k) Premarket Notification

K001250 APS SERIES DIALYZERS (WET MODELS), APS SERIES DIALYSIS (DRY MODELS)

CLEARED

Aug 16, 2000
119 days to decision

K001250 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k001250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 19, 2000
Decision date	Aug 16, 2000
Days to decision	119 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