

**K010131 PHD PERSONAL HEMODIALYSIS
INSTRUMENT-1M101, PHD WATER PRE-TREATMENT
KIT-1W605,PHD HARD PLUMBING KIT-1W604, PHD BLOOD
TUB**Mar 26, 2002
434 days to decisionK010131 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k010131/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jan 16, 2001
Decision date	Mar 26, 2002
Days to decision	434 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aksys, Ltd.
Location	Lincolnshire, IL, US
Contact	JAN L ZORN
510(k) history	1 submissions · 1 cleared · 2002-2002

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