

**K013562 AURORA SYSTEM 1000 SERIES HOME SELF-CARE
SINGLE PATIENT DELIVERY SYSTEM**Dec 12, 2002
412 days to decisionK013562 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k013562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 26, 2001
Decision date	Dec 12, 2002
Days to decision	412 days
Third-party review	No
Summary / Statement	Summary
Other names	MODELS- SYS 1000, L3 WITH N100 ARM, 4B SOFTWARE

APPLICANT

Company	Baxter Healthcare Corp
Location	Mchenry, IL, US
Contact	ROBERT L WILKINSON
510(k) history	505 submissions · 496 cleared · 1977-2019

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