

K163530 PrisMax Control UnitMay 3, 2017
138 days to decisionK163530 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k163530/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 16, 2016
Decision date	May 3, 2017
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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