

K162887 PrismaSATEJan 6, 2017
81 days to decisionK162887 · Product code: **KPO** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k162887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Oct 17, 2016
Decision date	Jan 6, 2017
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Healthcare Corporation
Location	Round Lake, IL, US
Contact	Kristen Bozzelli
510(k) history	61 submissions · 60 cleared · 2004-2025

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