

**K193482 PrisMax System Version 3**Mar 13, 2020  
87 days to decisionK193482 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k193482/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 17, 2019
Decision date	Mar 13, 2020
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baxter Healthcare Corporation</b>
Location	Round Lake, IL, US
Contact	Christopher Scavotto
510(k) history	61 submissions · 60 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193482/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 15, 2026