

**K191093 Isopure Dry Acid Dissolution System**Jan 22, 2020  
272 days to decisionK191093 · Product code: **KPO** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k191093/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialysate Concentrate For Hemodialysis (liquid Or Powder) (KPO)
Date received	Apr 25, 2019
Decision date	Jan 22, 2020
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Isopure, Corp.</b>
Location	Simpsonville, KY, US
Contact	Kevin Gillespie
510(k) history	5 submissions · 5 cleared · 2000-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191093/> 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 June 28, 2026