

**K112427 BICARB MIXING AND DISTRIBUTION SYSTEM**Jan 26, 2012  
156 days to decisionK112427 · Product code: **FIN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k112427/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tank, Holding, Dialysis (FIN)
Date received	Aug 23, 2011
Decision date	Jan 26, 2012
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Isopure, Corp.</b>
Location	Simpsonville, KY, US
Contact	KEVIN C 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/k112427/> 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