

**K112331 BIOPURE PORTABLE RO SYSTEMS**Jul 5, 2012  
328 days to decisionK112331 · Product code: **FIP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k112331/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Aug 12, 2011
Decision date	Jul 5, 2012
Days to decision	328 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arion Water, Inc.</b>
Location	Carver, MA, US
Contact	ROBERT LIVINGSTON
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112331/> 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 14, 2026