

**K042018 ACUTE PORTABLE EXCHANGE DEIONIZATION (PEDI) SYSTEM, CENTRAL PEDI SYSTEM, BACK-UP PEDI SYSTEM**Apr 15, 2005  
262 days to decisionK042018 · Product code: **FIP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k042018/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Subsystem, Water Purification (FIP)
Date received	Jul 27, 2004
Decision date	Apr 15, 2005
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Simply Clean Air &amp; Water, Inc.</b>
Location	Newington, CT, US
Contact	RAYMOND KOWALEC
510(k) history	1 submissions · 1 cleared · 2005-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042018/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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