

**K050609 AQUADEX SYSTEM**Nov 9, 2005  
244 days to decisionK050609 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k050609/>**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	Mar 10, 2005
Decision date	Nov 9, 2005
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chf Solutions, Inc.</b>
Location	Washington, DC, US
Contact	CHRIS SCAVOTTO
510(k) history	13 submissions · 13 cleared · 2002-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050609/> 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 27, 2026