

**K090682 EDWARDS AQUARIUS SYSTEM, MODEL GE-F098-00**Nov 19, 2009  
248 days to decisionK090682 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k090682/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 16, 2009
Decision date	Nov 19, 2009
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edwards Lifesciences Services GmbH</b>
Location	Stevenage, GB
Contact	NEIL R ARMSTRONG
510(k) history	3 submissions · 3 cleared · 2007-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090682/> 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 22, 2026