

**K082515 ASAHI REXEED-SX/LX DIALYZERS, MODELS: 13SX,  
15SX, 18SX, 21SX, 25SX, 13LX, 15LX, 18LX, 21LX**Oct 3, 2008  
31 days to decisionK082515 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k082515/>**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	Sep 2, 2008
Decision date	Oct 3, 2008
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Asahi Kasei Medical Co., Ltd.</b>
Location	Rockville, MD, US
Contact	DAVID L WEST
510(k) history	5 submissions · 5 cleared · 2005-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082515/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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