

**K143482 xevonta dialyzer**Mar 1, 2016  
449 days to decisionK143482 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k143482/>**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	Dec 8, 2014
Decision date	Mar 1, 2016
Days to decision	449 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>B. Braun Avitum AG</b>
Location	Allentown, PA, US
Contact	Giuliana Gavioli
510(k) history	5 submissions · 5 cleared · 2010-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143482/> 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 1, 2026