

**K100334 DIACAP POLYSULFONE HIFLO 23 HEMODILAYZER ,  
MODEL 72036811**Apr 22, 2010  
76 days to decisionK100334 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k100334/>**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	Feb 5, 2010
Decision date	Apr 22, 2010
Days to decision	76 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	ANGELA J CARAVELLA
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/k100334/> 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