

K083460 DIALOG WITH ADIMEA OPTIONFeb 18, 2010
454 days to decisionK083460 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k083460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Nov 21, 2008
Decision date	Feb 18, 2010
Days to decision	454 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	B. Braun Avitum AG
Location	Allentown, PA, US
Contact	BONNIE KINCAID, RAC
510(k) history	5 submissions · 5 cleared · 2010-2017

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