

**K133299 ACETIC ACID WAND, ACID WAND ASSEMBLY,
BICARBONATE WAND ASSEMBLY**Jul 7, 2014
255 days to decisionK133299 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k133299/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 25, 2013
Decision date	Jul 7, 2014
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care, North America - Renal Ther
Location	Waltham, MA, US
Contact	DENISE M OPPERMAN
510(k) history	1 submissions · 1 cleared · 2014-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133299/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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