

K121341 FRESENIUS 2008T HEMODIALYSIS MACHINE WITH BIBAG SYSTEMDec 6, 2012
217 days to decisionK121341 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k121341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 3, 2012
Decision date	Dec 6, 2012
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care North America
Location	Lexington, MA, US
Contact	DENISE OPPERMANN
510(k) history	43 submissions · 43 cleared · 1998-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121341/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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