

**K120017 FRESENIUS 2008 HEMODIAYSIS MACHINE WITH
BIBAG SYSTEM**Feb 2, 2012
30 days to decisionK120017 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k120017/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jan 3, 2012
Decision date	Feb 2, 2012
Days to decision	30 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

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