

K120505 FRESENIUS 2008T HEMODIALYSIS MACHINEMar 6, 2012
14 days to decisionK120505 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k120505/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Feb 21, 2012
Decision date	Mar 6, 2012
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care North America, Design Cente
Location	Waltham,, MA, US
Contact	DENISE OPPERMANN
510(k) history	5 submissions · 5 cleared · 2010-2013

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