

**K101715 FRESENIUS 2008T HEMODIALYSIS MACHINE MODEL
190573**Dec 21, 2010
186 days to decisionK101715 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k101715/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jun 18, 2010
Decision date	Dec 21, 2010
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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