

K093902 MODIFICATION TO:FRESENIUS 2008T HEMODIALYSIS MACHINE, MODEL 190573May 27, 2010
156 days to decisionK093902 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k093902/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Dec 22, 2009
Decision date	May 27, 2010
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093902/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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