

**K111639 FRESENIUS 2008T HEMODIALYSIS MACHINE**Oct 21, 2011  
130 days to decisionK111639 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k111639/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jun 13, 2011
Decision date	Oct 21, 2011
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fresenius Medical Care</b>
Location	Lexington, MA, US
Contact	DENISE OPPERMANN
Website	<a href="http://www.fmc-ag.com/">http://www.fmc-ag.com/</a>
510(k) history	7 submissions · 7 cleared · 2000-2024

Fresenius Medical Care is a global provider of dialysis products and services. The company operates with a manufacturing facility in Lexington, US. It specializes in Gastroenterology & Urology devices for kidney replacement therapy and renal care. The company has received FDA 510(k) clearances from total submissions. All submissions focus on Gastroenterology & Urology devices. Fresenius Medical Care's regulatory activity spans from 2000 to 2024, with its most recent clearance in 2024, demonstrating continued innovation in renal care technologies. The company's cleared dev...

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