

**K131908 2008T HEMODIALYSIS MACHINE WITH OPTIONAL CRIT-LINE MONITOR (CLIC)**Oct 11, 2013  
107 days to decisionK131908 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k131908/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Jun 26, 2013
Decision date	Oct 11, 2013
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Fresenius Medical Care Renal Therapies Group, LLC</b>
Location	Waltham, MA, US
Contact	DENISE OPPERMANN
Website	<a href="https://www.freseniusmedicalcare.com">https://www.freseniusmedicalcare.com</a>
510(k) history	51 submissions · 51 cleared · 2013-2026

Fresenius Medical Care Renal Therapies Group, LLC is a medical device manufacturer based in Waltham, US. The company specializes in renal therapy and dialysis technologies. The company has received FDA 510(k) clearances from total submissions since 2013. 96% of submissions focus on Gastroenterology & Urology devices, reflecting the company's core expertise in dialysis and renal replacement therapies. The latest clearance was in 2026, confirming active regulatory engagement. Recent cleared devices include hemodialysis systems, dialyzers, body composition monitors, and dial...

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k131908/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 8, 2026