

**K141997 CRIT-LINE IV SYSTEM**Apr 1, 2015  
252 days to decisionK141997 · Product code: **KOC** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k141997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Blood Circuit, Hemodialysis (KOC)
Date received	Jul 23, 2014
Decision date	Apr 1, 2015
Days to decision	252 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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