

# K201207 CombiSet SMARTECH Hemodialysis Blood Tubing Set with attached Priming Set and Integrated Crit-Line Technology, CombiSet SMARTECH Hemodialysis Blood Tubing Set with attached Priming Set and Intergrated Crit-Line Technology, no Heparin Line

Sep 18, 2020  
136 days to decision

K201207 · Product code: **KOC** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k201207/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Blood Circuit, Hemodialysis (KOC)
Date received	May 5, 2020
Decision date	Sep 18, 2020
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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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	50 submissions · 50 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...