

K124035 2008K@HOME HEMODIALYSIS MACHINEJul 3, 2013
187 days to decisionK124035 · Product code: **ONW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k124035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialysis System For Home Use (ONW)
Date received	Dec 28, 2012
Decision date	Jul 3, 2013
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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