

**K070049 FRESENIUS 2008K @HOME WITH WIRELESS
WETNESS DETECTOR**Feb 3, 2011
1491 days to decisionK070049 · Product code: **ONW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k070049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemodialysis System For Home Use (ONW)
Date received	Jan 4, 2007
Decision date	Feb 3, 2011
Days to decision	1491 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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