

**K121421 FRESENIUS 2008K HOME HEMODIALYSIS MACHINE
WITH WIRELESS WETNESS DETECTOR (WETALERT)**Jan 17, 2013
248 days to decisionK121421 · Product code: **ONW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k121421/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hemodialysis System For Home Use (ONW)
Date received	May 14, 2012
Decision date	Jan 17, 2013
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Medical Care North America, Design Cente
Location	Waltham,, MA, US
Contact	COLLEEN DURRAN
510(k) history	5 submissions · 5 cleared · 2010-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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