510K SUMMARY

K121421
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JAN 17 2013

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content in this 510(k) summary has been provided in conformance with 21 CFR Part 807.92

Submitter's Information:

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Contact Person:	Denise Oppermann Senior Director, Regulatory Affairs – Devices
Date of Preparation:	17 January 2013

Device Name:

Trade Name:	**2008K@home Hemodialysis Machine with Wireless Wetness Detector**
Common Name:	Hemodialysis Machine
Product Code/Classification Panel:	KDI, ONW, ODX / Gastroenterology - Urology
Classification Name:	High Permeability Hemodialysis System Class II per §876.5860

Legally Marketed Predicate Device (unmodified devices):

The Fresenius 2008K@home Hemodialysis Machine with Wireless Wetness Detector (WetAlert) system (K070049) originally 03 February 2011.

Device Description:

The 2008K@home Hemodialysis Machine with Wireless Wetness Detector is intended for short term (acute) and long term (chronic) dialysis treatment in a clinical facility and at home. In the home, a trained and qualified person must observe treatment as prescribed by a physician.

The 2008K@home Hemodialysis Machine is designed to provide hemodialysis treatment by controlling and monitoring both the dialysate and extracorporeal blood circuits. In the extracorporeal blood circuit, blood is continuously circulated from the patient through a dialyzer, where toxins are filtered out through a semi-permeable membrane, and returned to the patient. During this process, the extracorporeal blood circuit is monitored for venous and arterial blood pressures, and for the presence of air and blood.

The Wireless Wetness Detector system (branded as WetAlert) is an optional accessory to the 2008K@home. It is a multi-use, battery-powered device capable of detecting fluid leaks (i.e., blood or other conductive fluids). During treatment, the Wireless Wetness Detector transmits radio signals to the corresponding 2008K@home Hemodialysis Machine and will alert the 2008K@home Hemodialysis Machine if it detects a blood or water leak. During a wetness alarm, the 2008K@home Hemodialysis Machine will automatically stop the blood pump, close the venous clamp, and sound an alarm.

Modifications to the previously cleared 2008K@home with Wireless Wetness Detector system include:

- 2008K@home Hemodialysis Machine- Replace the single receiver system with a dual antenna/receiver configuration for reception durability.
- Wireless Wetness Detector- Change the Wireless Wetness Detector device body from a solid over-molded enclosure to a hollow, lighter weight, two-part bonded plastic case.
- Wireless Wetness Detector- Modify the software to enhance the electrostatic immunity of the device.
- 2008K@home WetAlert Home User's Guide- The guide is being separated into a clinical and a home version. Additional modifications include instructions and descriptions of changes.

Indications for Use:

The modified 2008K@home with Wireless Wetness Detector (WetAlert) system has the same indications for use as the unmodified device.

2008K@home Hemodialysis Machine Indications for Use

The Fresenius 2008K@home is indicated for acute and chronic dialysis therapy in an acute or chronic facility. The 2008K@home is also indicated for hemodialysis in the home and must be observed by a trained and qualified person as prescribed by their physician.

Wireless Wetness Detector (Wet Alert) Indications for Use

The Wireless Wetness Detector is indicated for use with the Fresenius 2008K@home hemodialysis machine and is an optional accessory to aid in the detection of blood and

water leaks during hemodialysis. Home hemodialysis using the detector must be observed by a trained and qualified person as prescribed by their physician.

Technological Characteristics:

The modifications to the 2008K@home Hemodialysis Machine and Wireless Wetness Detector do not change the technological characteristics of either device. The principles of operation and the performance specifications remain the same as the unmodified devices. The modifications to the 2008K@home machine are made to enhance the reception from the Wireless Wetness Detector. The modifications to the Wireless Wetness Detector are being implemented to enhance durability without reducing battery life. The performance data described below demonstrate that the modified Fresenius 2008K@home with Wireless Wetness Detector (WetAlert) system is substantially equivalent to the unmodified version (K070049)

Performance Data:

The performance of the modified 2008K@home machine and Wireless Wetness Detector (WetAlert) system was evaluated according to existing FMCNA procedures, protocols, declared performance standards and guidelines of the quality system regulation (21 CFR 820). Design verification and validation tests were conducted to ensure that the modifications described in this submission did not affect the essential performance of the devices and the devices function as intended.

Testing included performance, safety, reliability and usability of the 2008K@home machine and the Wireless Wetness Detector. The evaluation involved wireless verification and performance, electromagnetic emissions and immunity and mechanical testing. Usability testing was also conducted to assure safe and effective use by the intended users. The results of the usability testing did not prompt additional changes. All testing of the 2008K@home and the Wireless Wetness also Detector met the acceptance criteria.

Conclusion:

The performance data demonstrate that the 2008K@home with Wireless Wetness Detector (WetAlert) is as safe and effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 17, 2013

Fresenius Medical Care North America
% Ms. Denise Oppermann
Senior Director, Regulatory Affairs - Devices
920 Winter Street
WALTHAM MA 02451-1457

Re: K121421
Trade/Device Name: Fresenius 2008@home Hemodialysis Machine
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: ODX, ONW, KDI
Dated: January 15, 2013
Received: January 16, 2013

Dear Ms. Oppermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K121421

Device Name:

Fresenius 2008K@home Hemodialysis Machine

Indications for Use:

2008K@home Hemodialysis Machine Indications for Use

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Note: A copy of this 'Indications for Use Statement' is also provided in Appendix 1.

☒ Prescription Use (Per 21 CFR 801 Subpart D) AND/OR ☐ Over-the-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121421