



510(k) Summary

JUL 03 2013

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

5.1 Submitter's Information

Name: Fresenius Medical Care North America
Address: 920 Winter Street
Waltham, MA 02451-1457
Phone: (781) 699-4479
Fax: (781) 699-9635
Contact Person: Denise Oppermann, Senior Director
Regulatory Affairs - Devices
Renal Therapies Group
Date of Preparation: 27 December 2012

5.2 Device Name

Trade Name: Fresenius 2008K@home Hemodialysis
Machine with bibag System
Common Name: Hemodialysis Delivery System
Classification Name: High Permeability Hemodialysis System
Classification Number: Class II per § 876.5860
Product Code/Classification Panel: 78 KDI/Gastroenterology/Urology Panel

5.3 Legally Marketed Predicate Devices

Fresenius 2008K@home Hemodialysis Machine (K121421 – under review) and
Fresenius 2008T.Hemodialysis Machine with bibag System (K121341).



5.4 Device Description

The 2008K@home Hemodialysis Machine with bibag System 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 with bibag System allows operators the option to prepare a saturated sodium bicarbonate solution online through automated mixing of dialysis grade water and dry sodium bicarbonate powder within the bibag source disposable. The bibag System comprises: (1) the sodium bicarbonate concentrate generator (known as the bibag module); and (2) the single-use disposable bag of dry sodium bicarbonate concentrate. A specialized bibag connector with a door is used to connect the single-use bibag disposable (650g/900g) filled with USP grade dry sodium bicarbonate powder to the bibag connector. The 2008K@home Hemodialysis Machine draws dialysis grade water into the bibag to produce a saturated solution of sodium bicarbonate online. This online generation of sodium bicarbonate can only be performed using a specially modified Fresenius 2008K@home Hemodialysis Machine with bibag System and can only be used with 45x (1:44) dilution. The bibag cannot be used with non-Fresenius hemodialysis machines capable of using cartridge type dry sodium bicarbonate because of the unique connection between the bibag disposable, the bibag connector, and the hemodialysis machine.

Additionally, this submission includes minor hardware/software changes to the proposed device: Active pressure regulation, Acid/Heat Disinfect button; simplified Acid Clean program and alternate LCD display.

5.5 Indications for Use

2008K@home Hemodialysis Machine:

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.

bibag System:

The Fresenius Medical Care bibag system is used with Fresenius Medical Care three stream proportioning hemodialysis systems equipped with the bibag module such as the 2008K@home Hemodialysis Machine and is indicated for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag System is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

**Wireless Wetness Detector (Wet Alert):**

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.

5.6 Technological Characteristics

The technological characteristics of the proposed device are summarized in context with the named predicate devices:

2008K@home Hemodialysis Machine with Wet Alert (K121421 – under review)

The modified device has the same operating principle, fundamental scientific technology, and is comparable in key safety and effectiveness and quality assurance features.

All existing water requirements, module options, functional options, performance limits, control parameters, compatible bloodlines, and language options remain unchanged from the predicate device.

The following technical specifications of the modified device remain the same as the predicate device:

- Safety system
- System performance
- Environmental Requirements
- User Interface (except for bibag System)
- Hardware and therapy settings
- Accessories (except for bibag disposable)
- Environmental Design
- Alarms (except for additional bibag System alarms)
- Accuracy and Controls
- Protection against Mechanical Hazard
- Protection against Electrical Hazard
- Protection against excessive temperature or other hazards
- Transportation and Storage conditions
- Manufacturing Location and manufacturing processes (assembly, fabrication, testing, shipping, installation and service).

Safety and effectiveness of the 2008K@home Hemodialysis Machine with bibag System is confirmed by system verification and validation testing to verify performance specifications, and user requirements, in conformance with applicable referenced FDA regulations and FDA-recognized industry and international standards.

A risk analysis (per ISO 14971) has been completed and potential hazards associated with the modifications are identified and mitigated. Mitigations are verified wherever applicable. All potential risks were deemed acceptable after mitigation.

bibag System:

The bibag System/module proposed for use with the 2008K@home Hemodialysis Machine is the same device cleared for use with the 2008T Hemodialysis Machine (K121341).

The 2008K@home Hemodialysis Machine with bibag System has the following key similarities to the predicate device (K121341):

- Intended Use
- Operating Principle
- Fundamental Scientific Technology: configuration, hydraulics, safety features (control, monitoring, alarms)
- Accessories – bibag disposable

5.7 Performance Data

The performance of the modified device described in this submission was evaluated according to existing FMCNA procedures, protocols, declared performance standards and guidelines of the quality system regulation (21 CFR Part 820). Design verification and validation tests were conducted to ensure that the modifications did not affect the essential performance of the device and the device functions as intended.

The following tests were conducted for the modified device:

5. **System and Software Verification and Validation Testing**
 - Functional Verification and Software Validation
 - Software Verification (Functional Tests)
 - Regression
 - Safety Systems Verification
 - Simulated Dialysis Treatment
 - Production Test Procedure
 - Unstructured and Static Code Verification
 - System Performance
 - Heat Disinfection Testing
 - Chemical Testing
6. **System Safety**
 - Equipment Safety
 - Electromagnetic Compatibility
7. **Reliability**
 - Accelerated Life Testing
 - Mechanical Life Testing
 - Elevated Temperature Testing
8. **Summative Usability**

5.8 Conclusion

Test results demonstrated that the modified 2008K@home Hemodialysis Machine with bibag System functions as intended and met pre-determined acceptance criteria. Results of system/software verification/validation testing, safety testing, reliability testing, summative usability study and risk analysis indicate that differences between the 2008K@home Hemodialysis Machine with bibag System and the predicate devices do not raise any new concerns with regard to safety or effectiveness.

FMCNA concludes that, within the meaning of the Medical Device Amendments Act of 1976, the 2008K@home Hemodialysis Machine with bibag System is substantially equivalent to the predicate devices.



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

July 3, 2013

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

Re: K124035
Trade/Device Name: 2008K@home Hemodialysis Machine with bibag System
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: ONW, ODX, and KPO
Dated: June 10, 2013
Received: June 11, 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 contact 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>. 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



Indications for Use Statement

510(k) Number (if known): K124035

Device Name:

2008K@home Hemodialysis Machine with bibag™ System

Indications for Use:

2008K@home Hemodialysis Machine:

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.

bibag System:

The Fresenius Medical Care bibag System is used with Fresenius Medical Care three stream proportioning hemodialysis systems equipped with the bibag module such as the 2008K@home Hemodialysis Machine and is indicated for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag System is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

Wireless Wetness Detector (Wet Alert):

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.

Prescription Use
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use
(21 CFR 801 Subpart C)

Benjamin R. Fisher -S
2013.07.03 14:49:56 -04'00'

(Division Sign-Off)
**Division of Reproductive, Gastro-Renal, and
Urological Devices**
510(k) Number K124035