DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 10, 2015

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Senior Director
920 Winter Street
Waltham, MA 02451

Re: K150708
Trade/Device Name: 2008K Hemodialysis Machine, 2008K@home Hemodialysis Machine, and 2008T Hemodialysis Machine
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, ONW
Dated: October 29, 2015
Received: October 30, 2015

Dear Denise 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 and Part 809); 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 and Part 809), please contact the Division of Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Herbert P. Lerner -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150708

Device Name

2008K Hemodialysis Machine, 2008K@home Hemodialysis Machine, and the 2008T Hemodialysis Machine

Indications for Use *(Describe)*

2008K Hemodialysis Machines:
The 2008K Hemodialysis Machine is indicated for acute and chronic dialysis therapy.

2008K@home Hemodialysis Machine:
The 2008K@home Hemodialysis Machine is indicated for acute and chronic dialysis therapy in an acute or chronic facility. The 2008K@home Hemodialysis Machine 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 (Optional):
The bibag System is used with three stream proportioning Hemodialysis Machines 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 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.

2008T Hemodialysis Machine:
The 2008T Hemodialysis Machine is indicated for acute and chronic dialysis therapy.

bibag System (Optional):
The bibag system is used with three stream proportioning Hemodialysis Machines equipped with the bibag module such as the 2008T Hemodialysis Machine and is intended for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

Crit-Line Clip Monitor (CLiC) (Optional):
The Crit-Line Clip Monitor is used with the 2008T Hemodialysis Machine to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The CLiC device measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the clinician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e., increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common complications of dialysis which include nausea, cramping and vomiting

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(K) SUMMARY

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 § 807.92.

5.1. Submitter's Information

Name: Fresenius Medical Care Renal Therapies Group, LLC
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
Preparation Date: March 5, 2015

5.2. Device Name

Trade Name:	2008K Hemodialysis Machine, 2008K@home Hemodialysis Machine, and the 2008T Hemodialysis Machine
Common Name:	Accessories, blood circuit, hemodialysis
Classification Name :	Hemodialysis system and accessories, Hemodialysis System for Home Use
Regulatory Class:	Class II per 21 CFR §
Product Code/ Classification Panel:	KDI/Gastroenterology–Urology, ONW/Gastroenterology–Urology

5.3. Legally Marketed Predicate Device

2008K Hemodialysis Machine	K994267
2008K@home Hemodialysis Machine	K124035
2008T Hemodialysis Machine	K131908

5.4. Device Description

This section includes an explanation of how the devices function, the concepts that form the basis for the devices, and the significant physical and performance characteristics of the devices, such as device design, material used, and physical properties.

5.4.1. Device Identification:

The 2008K Hemodialysis Machine, the 2008K@home Hemodialysis Machine, and the 2008T Hemodialysis Machine are the subject of this submission. These machines are variations of the same basic mechanisms and design concepts, having different user interfaces and/or mechanical sub-systems. The disposable devices used with these systems are not the subject of this submission.

5.4.2. Device Characteristics

The machines described in this submission are medical electrical systems. Software controls the functions of the machines, including fluid flow, mixing, heating, and alarms.

5.4.3. Environment of Use

All 2008 Series Hemodialysis Machines are designed to be used in healthcare facilities, including hospitals. The 2008K@Home Hemodialysis Machine is also intended to be used in the home environment. During home use, a trained and qualified person must observe patient treatment as prescribed by a physician.

5.4.4. Brief Written Description of the Device

Hemodialysis machines are used for performing dialysis therapy. The machines pump blood from the patient's body through an extracorporeal circuit which contains a semi-permeable membrane. This acts as an artificial kidney to transport toxins (diffusion) and excess water (ultrafiltration) from the blood into a separate fluid (dialysate) circuit. During this process, the extracorporeal blood circuit is monitored for venous and arterial blood pressures, and for the presence of air and blood. In the dialysate circuit, the dialysate concentrates are mixed with purified water, heated, degassed, and delivered to the dialyzer. Balancing chambers control the incoming flow and outgoing flow of the dialysate fluid during ultrafiltration.

5.4.5. Materials of Use

The machines' hydraulic systems are composed of the following indirect, prolonged contact, externally communicating materials:

Plastic/Rubber:

PAEK (Polyaryletherketone)
PEI (Polyetherimide)
PESU (Polyethersulfone)
PSU (Polysulfone)
PET (Polyethylene terephthalate)
PUR (Polyurethane)
PET (Polyethylene terephthalate)
PP (Polypropylene)
PPO (Polyphenylene oxide)

PPS (Polyphenylene Sulfide)
PPSU (Polyphenylsulfone)
PTFE (Polytetrafluoroethylene)
PVDF (Polyvinylidene fluoride)

EPDM (Ethylene Propylene Diene Monomer Rubber)
Silicone

Metals:

Stainless Steel
Titanium Tantalum
Tungsten

Glass:

Borosilicate Glass

The hydraulic lines of the machines are in contact with the dialysate circuit. The dialysate circuit has prolonged, indirect blood contact.

5.4.6. Key Performance Specifications/Characteristic

The key performance specification of the 2008K Hemodialysis Machine, the 2008K@home Hemodialysis Machine, and the 2008T Hemodialysis Machine remain identical to the predicate devices.

The following non-clinical testing was conducted to verify the modifications do not affect the key performance specifications of the machines:

Hardware Testing

- Electronic Functional Testing
  - Circuit Testing
- Mechanical Testing
  - Mechanical Functional Testing
  - Mechanical Reliability Testing
  - Mechanical Regression Testing

Software Verification and Validation

- Software Unit and Integration Testing
- Software Functional Verification and Validation Tests (including Simulated Dialysis Treatment Testing)

5.5. Intended Use

The 2008K Hemodialysis Machine, 2008K@home Hemodialysis Machine, and the 2008T Hemodialysis Machine are intended to be used for acute and chronic dialysis therapy.

5.6. Indications for Use

The following indication for use statements for each of the Hemodialysis Machines are provided for reference.

5.6.1. 2008K Hemodialysis Machine:

The 2008K Hemodialysis Machine is indicated for acute and chronic dialysis therapy.

5.6.2. 2008K@home Hemodialysis Machine:

The 2008K@home Hemodialysis Machine is indicated for acute and chronic dialysis therapy in an acute or chronic facility. The 2008K@home Hemodialysis Machine 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 (Optional):

The bibag System is used with three stream proportioning Hemodialysis Machines 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 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.

5.6.3. 2008T Hemodialysis Machine:

The 2008T Hemodialysis Machine is indicated for acute and chronic dialysis therapy.

bibag System (Optional):

The bibag system is used with three stream proportioning Hemodialysis Machines equipped with the bibag module such as the 2008T Hemodialysis Machine and is intended for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

Crit-Line Clip Monitor (CLiC) (Optional):

The Crit-Line Clip Monitor is used with the 2008T Hemodialysis Machine to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The CLiC device measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the clinician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e., increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common complications of dialysis which include nausea, cramping and vomiting

5.7. Comparison of Technological Characteristics with the Predicate Device

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

Safety system
System performance
Environmental Requirements
Accessories
Accuracy and Controls
Protection against Mechanical Hazard
Protection against Electrical Hazard
Protection against excessive temperature or other hazards
Transportation and Storage specifications

5.8. Performance Data

The performance of the modified devices described in this submission was evaluated according to existing FMC-RTG procedures, protocols, declared performance standards, and guidelines of the quality system regulation (21 CFR Part 820). Design verification tests confirmed that all design updates were effective and did not affect the essential performance of the devices and that the devices function as intended.

5.8.1. Hardware - Electronic Functionality Testing

Functional verification evaluations of the electronic circuit consisted of demonstrating effectiveness of the dialysate air detection circuit.

5.8.2. Hardware-Mechanical Testing

The mechanical evaluations consisted of:

- Functional verification testing to demonstrate effectiveness of the hydraulic system.
- System reliability testing to demonstrate appropriate repeated function.
- Regression verification testing to demonstrate (system) functional performance of the machines.

5.8.3. Software Verification and Validation Testing

Software evaluations consisted of:

- Unit level testing to demonstrate unit level software performance met software design specifications
- Integration testing to demonstrate the unit level software interacted as specified in software design specifications
- System level software verification testing to demonstrate the effectiveness of the software modifications and confirm operation of the machines

5.9. Conclusions

Test results demonstrated that the modified 2008K Hemodialysis Machine, 2008K@home Hemodialysis Machine, and 2008T Hemodialysis Machine function as intended and met the acceptance criteria. Results of performance testing do not raise any new concerns with regard to safety or effectiveness.