DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 26, 2016

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

Re: K153449
Trade/Device Name: 2008K2 Hemodialysis Machines
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: March 31, 2016
Received: April 1, 2016

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); 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 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,

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

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)*
K153449

Device Name
2008K2 Hemodialysis Machines

Indications for Use *(Describe)*
The 2008K2 Hemodialysis Machine is indicated for acute and chronic hemodialysis therapy in a healthcare facility.

Additional therapy options for patients receiving hemodialysis include: Isolated Ultrafiltration, Sustained Low Efficiency Dialysis (SLED), and low volume hemodialysis (patients weighing ≥ 20 kg and ≤ 40 kg). This machine accommodates the use of both low flux and high flux dialyzers. The SLED therapy option is not to be used for patients weighing ≤ 40 kg. The 2008K2 Hemodialysis Machine is not to be used for plasma replacement therapies, for patients weighing less than 20 kg, or for renal therapies using substitution fluid.

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
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Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs – Devices
Preparation Date:	27 November 2015

5.2. Device Name

Trade Name:	2008K2 Hemodialysis Machine
Common Name:	Dialyzer, High Permeability With Or Without Sealed Dialysate
Classification Name :	High Permeability Hemodialysis System
Regulatory Class:	Class II per 21 CFR § 876.5860
Product Code/Classification Panel:	KDI KDI/Gastroenterology-Urology

5.3. Legally Marketed Predicate Device

2008K Hemodialysis Machine, originally cleared under K994267. The 2008K Hemodialysis Machine was most recently cleared under K150708 for hardware, mechanical, software and labelling modifications required to address issues identified in the field.

5.4. Device Description

5.4.1. Device Identification:

The 2008K2 Hemodialysis Machine will be available in the configurations described in Table 1.

Table 1: 2008K2 Hemodialysis Machines

Product Line	Code	Part Number Description
2008K2	190610	2008K2 Hemodialysis System Online Clearance (OLC)/Diasafe Plus (DP)
2008K2	190628	2008K2 OLC only with Heparin Pump (HP)
2008K2	190630	2008K2 Machine, Short Cabinet, OLC/DP, HP
2008K2	190633	2008K2 Hemodialysis System, Optional Module*

*The optional module indicates a version where the heparin pump is placed in a lower cabin bay area.

5.4.2. Device Characteristics

The machine described in this submission is medical electrical equipment containing a programmable electrical medical system. Software controls the functions of the machines during hemodialysis treatment, including fluid flow, mixing, heating, and alarms.

5.4.3. Environment of Use

The 2008K2 Hemodialysis Machine is to be used in healthcare facilities.

5.4.4. Brief Written Description of the Device

The 2008K2 Hemodialysis machines is used for dialysis therapy. The machine pumps blood from the patient through an extracorporeal circuit containing a semi-permeable membrane (dialyzer). This membrane 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 2008K2 Hemodialysis Machine's hydraulic system is 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. No modifications to the dialysate circuit are proposed.

5.4.6. Key Performance Specifications/Characteristic

Key performance characteristics of the 2008K2 Hemodialysis Machine are:

- Blood flow rates
- Dialysis fluid flow rates
- Net fluid removal
- Dialysis time
- Dialysis fluid composition
- Dialysis fluid temperature
- Heparin delivery rate

5.5. Intended Use

The Fresenius 2008K2 Hemodialysis Machine is intended for acute and chronic dialysis therapy.

The intended use is identical to the predicate device's intended use.

5.6. Indications for Use

The 2008K2 Hemodialysis Machine is indicated for acute and chronic hemodialysis therapy in a healthcare facility.

Additional therapy options for patients receiving hemodialysis include: Isolated Ultrafiltration, Sustained Low Efficiency Dialysis (SLED), and low volume hemodialysis (patients weighing ≥ 20 kg and ≤ 40 kg). This machine accommodates the use of both low flux and high flux dialyzers. The SLED therapy option is not to be used for patients weighing ≤ 40 kg. The 2008K2 Hemodialysis Machine is not to be used for plasma replacement therapies, for patients weighing less than 20 Kg, or for renal therapies using substitution fluid.

5.7. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the 2008K2 Hemodialysis Machine are equivalent to the predicate device. Although modifications to functional board and the front panel board were necessary to accommodate additional keys on the 2008K^2 Machine, all other electrical components, mechanical components, hydraulic components, and safety and alarm monitoring systems are identical to the predicate device.

The following technical specifications of the 2008K2 machine 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
Manufacturing location
Manufacturing process (assembly, testing, shipping, installation, and service)

5.8. Performance Data

5.8.1. Biocompatibility Testing

Hydraulic components of the proposed device (i.e. valves, tubing, sensors and gauges, etc.) are in contact with the dialysate and are identical to the predicate device. Therefore, additional biocompatibility testing was not required.

5.8.2. Electrical Safety and Electromagnetic Compatibility (EMC)

The 2008K2 Hemodialysis Machine was evaluated to the electromagnetic compatibility (EMC) requirements of IEC 60601-1-2:2007 as well as to higher immunity test levels in supplemental testing to evaluate risk of additional healthcare facility EMI environmental considerations and risk of exposure to RF emitters.

Proposed modifications to the machine are limited to software and labeling changes, with no modifications to the power supply, machine insulation, grounding, or critical components. Therefore, the existing electrical safety testing of the 2008K2 Hemodialysis Machine was not affected by the proposed modifications, and no additional electrical safety testing was performed.

5.8.3. Software Verification and Validation Testing

System level software verification testing was performed to demonstrate the effectiveness of the software modifications and confirm operation of the machine.

5.8.4. Mechanical and Acoustic Testing

Mechanical testing included net fluid removal accuracy evaluations. Other mechanical testing was limited to that which supported software verification. Examples of these evaluations include:

- Dialysate flow rate accuracy
- Regression tests for verifying impact of an additional dialysate flow rate (flow accuracy and temperature testing)
- Heparin syringe plunger rates and dispensing volumes
- Simulated dialysis testing at the full range of dialysate and blood flow rates
- General system regression testing (production)

No acoustic testing was necessary for the modifications to the 2008K2 Hemodialysis Machine, which were limited to software and labeling modifications.

5.8.5. Other Bench Testing

The following evaluations were performed, but are not classified under electrical, software, or mechanical categories of testing:

- Microbiological purity testing of dialysis fluid
- A risk-based analysis of software updates to determine the impact of software modifications on usability.

5.8.6. Animal Studies

No animal studies were performed in support of the modifications.

5.8.7. Clinical Studies

No clinical studies were performed in support of the modifications.

5.9. Conclusions

The 2008K2 Hemodialysis Machine has equivalent indications for use, intended use and technological characteristics as the predicate device. The information provided in this submission, including design verification and validation, risk management, and electrical safety demonstrate the device functions as intended and support the determination of substantial equivalence. Differences between the 2008K2 Hemodialysis Machine and the predicate device do not raise any new concerns with regard to safety or effectiveness. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the proposed modified 2008K2 Hemodialysis Machines is substantially equivalent to the predicate device, the 2008K Hemodialysis Machine (K994267, K150708).