February 2, 2024

Fresenius Medical Care
Denise Oppermann
Vice President, Regulatory Affairs - North America
920 Winter Street
Waltham, Massachusetts 02451

Re: K231534
Trade/Device Name: 5008X Hemodialysis System
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI, KOC, FJK, FIP, NII
Dated: January 4, 2024
Received: January 4, 2024

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maura Rooney -S

Digitally signed by Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
5008X Hemodialysis System

Indications for Use *(Describe)*

Machine:

The 5008X™ system is indicated for intermittent hemodialysis treatment for patients with acute and chronic renal failure in a healthcare facility. Therapy options for patients weighing more than 40 kg include: Hemodiafiltration (HDF), Hemodialysis (HD), Hemofiltration (HF) and Isolated Ultrafiltration.

The 5008X Machine is equipped with a bibag system, but it may also be used with liquid bicarbonate using the connector included with the machine.

The bibag System is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. The bibag System is intended to be used as one component in the preparation of dialysate according to a physician's prescription in a 3-stream proportioning hemodialysis machine equipped with the bibag module.

The 5008X Machine is available equipped with a Crit-Line Clip (CLiC) Monitor System.

The optional CLiC system is used to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume 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 dialysis technician. 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 symptoms of dialysis which include nausea, cramping and vomiting.

DIASAFEPlusUS Filter:

The DIASAFE®plusUS is intended for the preparation of ultrapure dialysate and sterile, non- pyrogenic substitution fluid from pretreated water and is not intended to provide primary purification. Attention must still be given to the chemical and microbiological quality of water and concentrates and the maintenance of supply systems (e.g. RO system, central delivery system).

The microbiological quality (microbial count [CFU/mL] and endotoxin measurement [EU/mL]) of the incoming water should be < 200 CFU/mL and < 2 EU/mL, respectively.

The DIASAFE®plusUS can only be used with Fresenius Medical Care dialysis machines fitted for use with DIASAFE®plusUS.

5008X Tubing Set:

The blood tubing sets are intended to be used only with the Fresenius Medical Care 5008X Hemodialysis Device, which is indicated for intermittent hemodialysis treatment for patients with acute kidney injury or chronic kidney disease in a healthcare facility. Therapy options include: hemodiafiltration (HDF), hemodialysis (HD), hemofiltration (HF), and isolated ultrafiltration.

The blood tubing sets are indicated for use with a prescribed hemodialyzer. For use with a compatible hemodialyzer, as per the labeling.

Additional Indications for Use for the blood tubing set equipped with Twister AFRC

The Fresenius Twister Access Flow Reversing Connector (AFRC) is indicated for use during hemodialysis to reverse the blood flow to and from the arterial and venous vascular access devices in order to obtain an access flow measurement.

Additional Indications for Use for the blood tubing set equipped with CLiC

The blood tubing set is intended to be used with the Crit-Line Clip Monitor System (CLiC) on the 5008X Hemodialysis Device.

The CLiC is used to non-invasively measure hematocrit, oxygen saturation, and percent change in blood volume 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 dialysis technician. 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 symptoms of dialysis which include nausea, cramping and vomiting.

CitraSure Disinfectant:
CitraSure is intended for thermal disinfection of the Fresenius Medical Care 5008X Hemodialysis System when delivered and diluted per the 5008X heat disinfection program.

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) 996-9103
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, VP RA, NA
Preparation Date:	26 May 2023

5.2. Device Name

Trade Name:	5008X Hemodialysis System
Common Name:	Hemodialysis Delivery Device, including the Diasafe filter, bloodlines, disinfectant and accessories
Regulation Name:	High Permeability Hemodialysis System
Regulatory Class:	Class II per 21 CFR §876.5860
Product Code:	KDI, KOC, FJK, FIP, NII
Product Code Name:	Dialyzer, high permeability with or without sealed dialysate system; Accessories, blood circuit, hemodialysis; Set, tubing, blood, with and without anti-regurgitation valve; Subsystem, water purification; Disinfectant, dialysate delivery system
FDA Review Panel:	Gastroenterology-Urology

5.3. Legally Marketed Predicate Devices

None of the predicate devices listed below have been subject to any design-related recalls.

5.3.1. 5008X Machine Predicate Device

The predicate device for the 5008X Hemodialysis System is the 2008T BlueStar™ Hemodialysis system cleared under K222952. The legally marketed secondary predicate device, the Nephros OLpur H_2H Module (K112314), is included to support additional therapy modes. The legally marketed predicate device, Aksys PHD Personal Hemodialysis Instrument (K010131), is included to support the online bolus feature.

5.3.2. 5008X Bloodlines (also referred to as "Bloodline") Predicate Devices

The legally marked predicate device is the CombiSet SMARTECH Hemodialysis Bloodlines cleared under K201207. The legally marketed secondary predicate device is the CAREline Airless Hemodialysis Bloodlines cleared under K172238.

5.3.3. DIASAFE®*plus*US filter Predicate Device

Two (2) DIASAFE®*plus*US filters cleared under K182367 are used on the 5008X hemodialysis machine to filter dialysate.

5.4. Device Description

5.4.1. Device Identification:

The 5008X Hemodialysis System consists of the following:

- The 5008X hemodialysis machine
- Two (2) DIASAFE®*plus*US Filters (hereinafter referred to as the "Diasafe filter(s)")
- The 5008X Hemodialysis Bloodlines (hereinafter referred to as "5008X Bloodlines") are available in three (3) configurations:
  - 5008X HDF Hemodialysis blood tubing set catalog number 03-5100-7 (hereinafter referred to as the "Standard Bloodline")
  - 5008X HDF Hemodialysis blood tubing set with access flow reversing connector (Twister®) catalog number 03-5150-2 (hereinafter referred to as the "Twister Bloodline")
  - 5008X HDF Hemodialysis blood tubing set with CLiC™ blood chamber catalog number 03-5100-7C (hereinafter referred to as the "CLiC Bloodline")
- CitraSure™ Disinfectant

5.4.2. Device Characteristics

The 5008X Hemodialysis Machine is an electromechanical device. Software controls the machine during hemodialysis treatment, including fluid flow, mixing, heating, and alarms.

The Diasafe filter is a non-sterile dialysis fluid filter that produces ultrapure dialysate and sterile, non-pyrogenic substitution fluid as defined in ANSI/AAMI/ISO 11663. The filter reduces microbial contaminants including endotoxins in the dialysate during hemodialysis treatment. The Diasafe filters are installed and exchanged on the 5008X Hemodialysis Machines using the

DIAFIX™ Lock System. The DIAFIX™ Lock System is a standard feature on 5008X Hemodialysis Machines and is installed during machine production.

The 5008X Bloodlines are single-use, ethylene oxide (EO) sterilized bloodlines.

CitraSure™ disinfectant is a liquid chemical disinfectant for chemical heat disinfection of the 5008X Hemodialysis Machine.

5.4.3. Environment of Use

The 5008X Hemodialysis System including its components (Diasafe filters, bloodlines, disinfectant and accessories) is intended for use in healthcare facilities, such as hospitals and dialysis clinics where intermittent dialysis treatment is performed.

5.4.4. Brief Written Description of the Device

The 5008X Hemodialysis Machine provides hemodialysis treatment by controlling and monitoring both the dialysate circuit and the extracorporeal blood circuit. The machine pumps blood from the patient's body through an extracorporeal circuit, one component of which is the dialyzer. The dialyzer contains a semi-permeable membrane that uses diffusion to transfer toxins and ultrafiltration to transport excess water from the blood into the dialysate circuit. In this separate dialysate circuit, the dialysate concentrates are mixed with purified water, heated, degassed, filtered (Diasafe filters) and delivered to the dialyzer. Substitution fluid can also be delivered to the patient using the Bloodline if hemofiltration (HF) or hemodiafiltration (HDF) is being performed. Balancing chambers control the dialysate during treatment. During treatment, the extracorporeal blood circuit is monitored for venous and arterial blood pressures as well as for the presence of air and blood. The 5008X Hemodialysis Machine accommodates the following accessory devices and options:

- Accessory Devices
  - Diasafe Filter (K182367)
  - Liquid bicarbonate or the bi*b*ag (K162716) concentrate system (central delivery of bicarbonate is not available on the 5008X)
  - Acid concentrates compliant with ISO 13958
  - Dialyzers compliant with ISO 8637, may be used for HD. Fresenius Medical Care dialyzers indicated for HDF and HF must be used if HDF or HF is being performed.
  - 5008X Hemodialysis Bloodlines
  - 5008X Fluid Sampling Accessory
- Options
  - Patient Card and User Card
  - CLiC (Crit-Line in a Clip Monitor): K121599 (Stand-alone CLiC) and K131908 (CLiC with 2008T HD Machine)

– BTM (Blood Temperature Monitor)

5.4.5. Materials of Use

5.4.5.1. Machine and Diasafe Filters

The 5008X Machine and Diasafe filters are classified as externally communicating, blood path, indirect, prolonged contact (> 24 hours to 30 days) duration, (Category B) devices in accordance with FDA guidance document *Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* (04 September 2020). A list of the hydraulic materials for the machine is provided in Table 1.

Table 1: Machine Hydraulic Materials

Component Material	Material Type
Plastic/Rubber	PPE+PS (Polyphenylene ether + polystyrene) EPDM (Ethylene Propylene Diene Monomer Rubber) PP (Polypropylene) PVDF (Polyvinylidene fluoride) PVC (Polyvinyl chloride) PPSU (Polyphenylsulfone) PESU (Polyethersulfone) PPS (Polyphenylene Sulfide) PTFE (Polytetrafluoroethylene) PEEK (Polyetheretherketone) PAEK (Polyaryletherketone) FKM (Fluorinated, carbon-based synthetic rubber) Platinum Cross-linked Silicone
Metals	Titanium Stainless Steel
Other	Borosilicate Glass Graphite Ceramic

A list of Diasafe filter materials is provided in Table 2.

Table 2: Diasafe Filter Materials

Component	Material
Filter fiber	Polysulfone and Polyvinylpyrrolidone
Housing Cap/Flange	Polypropylene
Potting resin	Polyurethane
O-Ring Plastic Tabs Sealing Disc Ring	Silicone

5.4.5.2. 5008X Bloodlines

The 5008X Bloodlines are classified as externally communicating, circulating blood, prolonged contact (> 24 hours to 30 days) duration, (Category B) devices in accordance with FDA guidance document *Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* (04 September 2020). The materials for the bloodline components are listed in Table 3.

Table 3: Bloodline Materials

Component	Material
Tubing and Components	Polyvinylchloride (PVC) Polycarbonate (PC) Polypropylene (PP) Polyethylene (PE) Acrylonitrile Butadiene Styrene (ABS) Polyisoprene Silicone TPE Styrene/Butadiene Copolymer Polystyrene
Transducer Protector	Polyester Polybutylene Terephthalate (PBT) Polytetrafluoroethylene (PTFE) PC
Twister	Acrylic and XT Polyisoprene Silicone

Table 3: Bloodline Materials

Component	Material
Integrated Crit-Line Blood Chamber	PVC PE PC
Bonding Solvents	TetraMEK (95% Tetrahydrofuran/5% MEK) Cyclohexanone Loctite 3311

5.4.5.3. CitraSure Disinfectant

CitraSure disinfectant has no direct or indirect contact with the patient and is rinsed from the 5008X Machine after the disinfection cycle is complete. CitraSure is comprised of citric acid, lactic acid, malic acid, potassium sorbate, and sodium benzoate, and dialysis-quality water.

5.4.6. Key Performance Specifications/Characteristic

The key performance specifications and characteristics for the 5008X Machine, Diasafe Filter, 5008X Bloodline, and CitraSure disinfectant are outlined in Table 4.

Table 4: Key Performance Specifications/Characteristics

Feature	Specification/Characteristic
5008X Machine	
Maximum Blood Flow Rate	600 mL/min
Maximum Dialysate Flow Rate	1000 mL/min
Maximum Substitution Flow Rate	With AutoSub plus (automatic substitution): 400 mL/min With manual substitution: 600 mL/min
Net Fluid Removal	0–4000 mL/hr Accuracy: ± (1%UF + 0.15% of balanced fluid volume) Balanced fluid volume = substitution fluid flow + dialysate flow
Dialysis Time	Intermittent, typical time 4 hours
Dialysis Fluid Composition	Volumetric, selectable: (Maximum ranges) Acid adjustment range: 125–151 mEq/L Na+ Bicarbonate adjustment range: 25–40 mEq/L Bicarbonate (post-reaction, after mixing with the acid and purified water). Monitoring conductivity average accuracy: ± 1.5%

Table 4: Key Performance Specifications/Characteristics

Feature	Specification/Characteristic
Dialysis Fluid Temperature	Range 34°C–39°C. Fixed alarm window 33°C (or 32°C during BTM recirculation measurement and preparation) or above 40°C.
Diasafe Filter	
Bacterial and Endotoxin Filtration	Produces sterile, non-pyrogenic substitution fluid from dialysis fluid with a maximum incoming water quality of 200 CFU/mL (bacteria) and 2 EU/mL (endotoxin)
Maximum Number Disinfection Cycles	100 CitraSure cycles 13 Pure Bright Bleach cycles
Use Life	90 days maximum or if maximum disinfection cycles have been reached
5008X Bloodline	
Maximum Blood Flow Rate	600 mL/min
Minimum Labeled Arterial Pressure	−300 mmHg
Maximum Labeled Venous Pressure	+500 mmHg
Arterial Pump Segment [Inner/Outer Diameter (ID/OD)]	8.0 mm/12.0 mm
Twister Component	The Twister component facilitates measurement of a patient's access flow by reversing blood flow to and from the arterial and venous vascular access sites while maintaining a closed extracorporeal circuit
CLiC Chamber (Optional) – Hematocrit (HCT)	The measured HCT using the CLiC Bloodline has a standard deviation X2 of ≤3%, and an average bias of ≤1% (of the average HCT) as measured on control blood chambers
CLiC Chamber (Optional) – Oxygen Saturation (O_2 Sat)	The measured O_2 Sat using the CLiC Bloodline has a standard deviation X2 of ≤3%, and an average bias of ≤2% (of the average O_2 Sat) as measured on control blood chambers
CitraSure Disinfectant	
Minimum Disinfection Temperature	70ºC
Minimum Contact Time	10 minutes
Use Life	90 Days

Table 4: Key Performance Specifications/Characteristics

Feature	Specification/Characteristic
Shelf Life	2 years

5.5. Intended Use

The 5008X Hemodialysis System intended for use in acute and chronic hemodialysis therapy. Therapy options include hemodialysis (HD), hemodiafiltration (HDF), hemofiltration (HF), and isolated ultrafiltration (ISO).

5.6. Indications for Use

5.6.1. Machine

The 5008X system is indicated for intermittent hemodialysis treatment for patients with acute and chronic renal failure in a healthcare facility. Therapy options for patients weighing more than 40 kg include: Hemodiafiltration (HDF), Hemodialysis (HD), Hemofiltration (HF) and Isolated Ultrafiltration.

The 5008X Machine is equipped with a bibag system, but it may also be used with liquid bicarbonate using the connector included with the machine.

The bibag System is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. The bibag System is intended to be used as one component in the preparation of dialysate according to a physician's prescription in a 3-stream proportioning hemodialysis machine equipped with the bibag module.

The 5008X Machine is available equipped with a Crit-Line Clip (CLiC) Monitor System.

The optional CLiC system is used to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume 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 dialysis technician. 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 symptoms of dialysis which include nausea, cramping and vomiting.

5.6.2. Diasafe Filter

The DIASAFE®plus$_{US}$ is intended for the preparation of ultrapure dialysate and sterile, non-pyrogenic substitution fluid from pretreated water and is not intended to provide primary purification. Attention must still be given to the chemical and microbiological quality of water and concentrates and the maintenance of supply systems (e.g. RO system, central delivery system).

The microbiological quality (microbial count [CFU/mL] and endotoxin measurement [EU/mL]) of the incoming water should be < 200 CFU/mL and < 2 EU/mL, respectively.

The DIASAFE®plus$_{US}$ can only be used with Fresenius Medical Care dialysis machines fitted for use with DIASAFE®plus$_{US}$.

5.6.3. 5008X Bloodlines

The bloodlines are intended to be used only with the Fresenius Medical Care 5008X Hemodialysis Device, which is indicated for intermittent hemodialysis treatment for patients with acute kidney injury or chronic kidney disease in a healthcare facility. Therapy options include: hemodiafiltration (HDF), hemodialysis (HD), hemofiltration (HF), and isolated ultrafiltration.

The blood tubing sets are indicated for use with a prescribed hemodialyzer. For use with a compatible hemodialyzer, as per the labeling.

Additional Indications for Use for the blood tubing set equipped with Twister AFRC

The Fresenius Twister Access Flow Reversing Connector (AFRC) is indicated for use during hemodialysis to reverse the blood flow to and from the arterial and venous vascular access devices in order to obtain an access flow measurement.

Additional Indications for Use for the blood tubing set equipped with CLiC

The blood tubing set is intended to be used with the Crit-Line Clip Monitor System (CLiC) on the 5008X Hemodialysis Device.

The CLiC is used to non-invasively measure hematocrit, oxygen saturation, and percent change in blood volume 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 dialysis technician. 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 symptoms of dialysis which include nausea, cramping and vomiting.

5.6.4. CitraSure Disinfectant

CitraSure is intended for thermal disinfection of the Fresenius Medical Care 5008X Hemodialysis System when delivered and diluted per the 5008X heat disinfection program.

5.7. Comparison of Technological Characteristics with the Predicate Device

5.7.1. 5008X Hemodialysis Machine

The following technological characteristics of the 5008X Hemodialysis Machines are equivalent to the 2008T BlueStar predicate device:

- Indications for Use
- bi*b*ag
- Blood Pressure Monitor (BPM)

- BTM
- Online Clearance Monitor (OCM)
- Recirculation measurement
- CLiC Monitor System (optional)
- HD and ISO therapy modes

The following technological characteristics of the 5008X Hemodialysis Machines are equivalent to the Nephros OLpur H_2H Module predicate device:

- Intended Use
- Filtration of dialysate to generate sterile, non-pyrogenic substitution fluid
- HDF and HF therapy modes

5.7.2. Diasafe Filter

The following technological characteristics of the Diasafe filter are substantially equivalent to those of the predicate Diasafe filter (K182367):

- Indications for Use
- Technological Characteristics
- Design
- Performance Requirements

5.7.3. 5008X Bloodline

The following technological characteristics of the 5008X Bloodlines are substantially equivalent to those of the predicate CombiSet SMARTECH Hemodialysis Bloodlines (K201207) and secondary predicate CAREline Airless Hemodialysis Bloodlines (K172237):

- Indications for Use
- Technological Characteristics
- Design
- Performance Requirements

5.8. Sterilization Testing

5.8.1. 5008X Hemodialysis Machine and Diasafe Filters

The 5008X Hemodialysis Machine and Diasafe filters are provided non-sterile. These components are disinfected with either CitraSure Disinfectant or Pure Bright Bleach using the pre-programmed machine disinfection cycle. The machine disinfection cycle has been validated to ensure an appropriate log reduction of bacteria and prevention of biofilm overgrowth in the hydraulics of the machine.

5.8.2. 5008X Bloodline

The 5008X Bloodlines are sterilized by exposure to 100% ethylene oxide (EO). The sterility assurance level (SAL) is 10^{-6}. Sterility and non-pyrogenicity are claimed for the fluid pathway of the bloodline.

5.8.2.1. Bloodline EO Residual Testing

Residual testing for EO and ethylene chlorohydrin (ECh) was performed in accordance with *AAMI/ANSI/ISO 10993-7:2008/(R)2012 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*. Acceptable results (i.e., < 4.6 mg/device for EO and ECh) were obtained for the subject bloodlines.

5.8.2.2. Bloodline Bacterial Endotoxin (Pyrogenicity) Testing

The subject bloodlines were tested for bacterial endotoxin (pyrogenicity) with Limulus Amebocyte Lysate (LAL) and determined to be non-pyrogenic (< 20 EU/device) in accordance with *ANSI/AAMI/ST72:2011/(R)2016 Bacterial Endotoxins – Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing.*

5.8.2.3. Bloodline Sterile Barrier Testing

Sterility of the blood pathway is maintained by the sterile fluid path of the device itself which includes the following components:

- Vented Caps
- Transducer Protectors (TPs)
- Tubing and all other components that make up the structural integrity of the bloodline's fluid path

The vented caps were qualified as part of the sterile barrier by microbial challenge tests in accordance with ANSI/AAMI/ISO 11607-1.

The TPs were qualified as part of the sterile barrier by a viral penetration test adapted from ASTM F1671-13.

The tubing and other components were qualified as part of the sterile barrier through the structural integrity test adapted from ISO 8638 and ASTM F2096-11. Testing was performed on samples after aging and distribution simulation.

5.9. Performance Data

5.9.1. 5008X Hemodialysis Machine

Performance testing to support the determination of substantial equivalence of the 5008X Machine is summarized in Table 5.

Table 5: 5008X Machine Performance Testing Summary

Test Conducted	Test Objective
System Level Performance Testing	Ensure the device performs in accordance with the product requirements and design inputs
Performance to Standards	Ensure the device conforms to the applicable standards: 60601-2-16:2018, 60601-1-8, 60601-1-2, AIM 7351731, and 60601-1
Interface Verification	Ensure the interfaces of the device function as intended when connected to the components and accessories of the system
Ship Testing	Verify that the device packaging protects the device from damage during shipment and storage
Disinfection Validation Testing	Ensure the disinfection cycles preset in the machine properly reduce microorganism populations
Material Compatibility	Ensure that the materials of the machine are compatible with the chemicals that they contact.

5.9.2. Diasafe Filter

Performance testing to support the determination of substantial equivalence of the Diasafe filter is summarized in Table 6.

Table 6: Diasafe Filter Performance Testing Summary

Test Conducted	Test Objective
Bacteria Retention	Verify that the Diasafe filter can produce ultrapure dialysate from dialysis fluid spiked with bacteria exceeding the allowable limit of < 200 CFU/mL (ANSI/AAMI RD52)
Endotoxin Retention	Verify that the Diasafe filter can produce ultrapure dialysate from dialysis fluid spiked with endotoxin exceeding the allowable limit of < 2 EU/mL (ANSI/AAMI RD52)
Ultrafiltration Rate	Verify that the Diasafe filter has an acceptable aqueous Ultrafiltration rate (K_{UF})
Substitution Fluid Composition	Measure the composition of substitution fluid after passing through two (2) Diasafe filters

Table 6: Diasafe Filter Performance Testing Summary

Test Conducted	Test Objective
Chemical Contaminants	Verify that the proposed device does not contribute unacceptable levels of chemical contaminants (elemental or ionic)

5.9.3. 5008X Bloodline

Performance testing for the 5008X Bloodlines was conducted in accordance with ISO 8638:2010 and Guidance for Industry and FDA Staff, Hemodialysis Blood Bloodlines – Premarket Notification [510(k)] Submissions (23 April 2008). Testing conducted to support the determination of substantial equivalence of the 5008X Bloodline is summarized in Table 7.

Table 7: 5008X Bloodline Performance Testing Summary

Test Conducted	Test Objective
Structural Integrity	Demonstrate that the bloodlines can withstand 1.5X the labeled maximum positive and negative pressures
Pump Segment Performance and Endurance Test	Evaluate performance characteristics of the bloodline pump segment over the range of inlet pressures (normally 0 mmHg to −250 mmHg), flow rates and treatment time. There is no flow at 0 mmHg; therefore, the pump segment was not evaluated at that flow rate. The blood pump segment does not break or detach at maximum blood flow rates of 600 mL/min and pressures (−300 mmHg inlet pressure and +760 mmHg outlet pressure) for 12 hours.
Simulated Use	Demonstrate that bloodlines perform with no tubing failures (kinking, collapsing, or disconnection) under simulated use conditions for not less than 4 hr.
Needle and Needleless Access Port	Demonstrate that the needle and needleless access ports can withstand 1.5X the labeled maximum and minimum pressures after being punctured with the largest gauge needle (21 gauge) recommended in the labeling per ISO 8638:2010.
DIN Connectors	Demonstrate that the DIN connectors do not leak when subjected to fluid pressure of 300–330 kPa ISO 80369-7:2016 specifies the test method, but it does not specify requirements for hemodialyzer blood compartment port connectors. However, the liquid leakage test from this standard has been adopted using the reference connector from ISO 8638:2010 to test the DIN connectors for this device.

Table 7: 5008X Bloodline Performance Testing Summary

Test Conducted	Test Objective
Male and Female Luer connectors	Demonstrate that the Luer connectors of the bloodlines meet the dimensional and performance requirements of ISO 80369-7 2016 (Sections 5 and 6)
Visual Inspection After Simulation of Transport	Demonstrate that shipping case, packaging configuration, and palletization pattern maintain the product's structural integrity during manual handling and motorized freight. Verify that there are no detached or missing caps, kinks in tubing, damages to components and/or tubing after shipping.
Tensile Testing	Demonstrate that all bonded engagements in the bloodlines between components, and between components and tubing can withstand a tensile force of 16N for main line tube connections, 152N for arterial pump tube connections, 144N for substitution pump tube connections, 11N for administration line tube connections, and 13N for access line tube connections
Labeling Content per FDA Blood Tubing Set Guidance and ISO 8638	Verify the Instructions for Use, color coded components, unit labels, shipping carton graphics, and case labels for the bloodlines meet the requirements of ISO 8638:2010 and *Guidance for Industry and FDA Staff: Hemodialysis Blood Tubing Test – Premarket Notification [510(k)] Submissions* (April 2008).
Readability of Barcode with Human Readable Identification Codes	Demonstrate that the barcode information on the outer container labels and unit labels for the bloodlines is capable of being scanned.
Transparency of Transducer Protector (TP)	Demonstrate that the machine side of the TP is clear to allow for visual inspection of blood contamination during use.
TP and Pressure Dome Leak	Demonstrate that the TP and pressure dome are capable of maintaining a secure and leak-free connection to the hemodialysis machine when subjected to 2x the maximum labelled pressure for 60 min as per ISO 8638 (with FDA recommendations).
Viral Retentiveness for TP	Demonstrate that the membrane inside the TP can prevent the passage of bacteriophage (Φ X174) from the patient side to the machine side up to a pressure of 600 mmHg for 1 hr.
Measure Gap Between Lenses	Demonstrate that the distance between the lenses from the CLiC Blood Chamber is within the specification of 0.078 ± 0.005 in.
Functional CLiC Chamber (Hematocrit)	The measured hematocrit (HCT) using the CLiC Bloodline has a standard deviation X2 of $\leq 3\%$, and an average bias of $\leq 1\%$ (of the average HCT) as measured on control blood chambers.

Table 7: 5008X Bloodline Performance Testing Summary

Test Conducted	Test Objective
Functional CLiC Chamber (O_2 Sat)	The measured O_2 Sat using the CLiC Bloodline has a standard deviation X2 of $\leq 3\%$, and an average bias of $\leq 2\%$ (of the average O_2 Sat) as measured on control blood chambers.
Tubing Compliance	Demonstrate that tubing is capable of being occlusively clamped by the venous line clamp of the dialysis machine.
Clamp Occlusion	Demonstrate that tubing is capable of being occlusively clamped by the bloodline clamps.
Twister (Rotation and Torque)	Demonstrate that the Twister component can twist and lock to $180° \pm 1°$ to reverse the blood flow, and that the torque required ≤ 7 inch-pound.
Check Valve (Cracking Pressure and Pressure Drop)	Demonstrate that the opening pressure (cracking pressure) of all the check valves is lower than 400 mbar. Demonstrate that the antisiphon valves present a pressure drop in a specific range when the substitution fluid is pumped through the valve at a certain flow rate.
Tube (Transparency, Resistance to Kinking, Clamping and Patency)	Demonstrate the transparency of the tube is evaluated observing the interface of air and liquid during the passage of 0.02 mL air bubble. Demonstrate no kinking of a tube at the maximum expected bend radius of 2.5 cm is evaluated measuring the percentage of flow reduction against the tube curved. Demonstrate the performance of the tube to resist clamp occlusions is evaluated subjecting the sample at a desired pressure and alternatively occluded with a clamp for a defined number of cycles. Demonstrate the performance of the tube to maintain its patency after being clamped and then reopened is evaluated measuring the flow reduction of the re-opened tube against the tube not clamped.
Air Bubble Trapping	Demonstrate that the Venous Chamber is able to trap incoming air bubbles larger than 20 µL.

5.9.4. Biocompatibility Testing

Biocompatibility testing for the 5008X System patient contacting components was conducted in accordance with ISO 10993-1:2018 and FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" (04 September 2020). The following testing was conducted to support the biological safety of the 5008X System:

- 5008X Machine
  - Cytotoxicity
  - Sensitization, Guinea Pig Maximization

  - Intracutaneous Irritation
  - Material-Mediated Pyrogenicity
  - Systemic Toxicity
  - Hemocompatibility, ASTM Hemolysis (Indirect)
  - Chemical Characterization
- Diasafe Filter
  - Cytotoxicity, Neutral Red Uptake
  - Sensitization, Guinea Pig Maximization
  - Intracutaneous Irritation
  - Material-Mediated Pyrogenicity
  - Hemocompatibility, ASTM Hemolysis (Indirect)
  - Subchronic Toxicity
  - Genotoxicity, (bacterial reverse mutation and mouse lymphoma)
  - Chemical Characterization
- 5008X Bloodlines:
  - Cytotoxicity, Neutral Red Uptake
  - Sensitization, Guinea Pig Maximization
  - Intracutaneous Irritation
  - Material-Mediated Pyrogenicity
  - Hemocompatibility, ASTM Hemolysis (Direct and Indirect)
  - Hemocompatibility, Dynamic (Mechanical) Hemolysis
  - Hemocompatibility, Complement Activation
  - Hemocompatibility, Platelet and Leukocyte Count
  - Hemocompatibility, Partial Thromboplastin Time
  - Chemical Characterization

5.9.5. Human Factors Validation Testing

Human Factors validation testing performed on the 5008X System ONLINE Features found no impact on the safe and effective use of ONLINE features. FMCRTG concludes that the system is safe and effective for the intended users, uses, and use environments.

5.9.6. Electrical Safety and Electromagnetic Compatibility (EMC)

The 5008X Hemodialysis Machine was evaluated for electromagnetic compatibility (EMC) in accordance with IEC 60601-1-2:2014. Additional electrical testing was conducted in accordance with AIM 7351731.

5.9.7. Software Verification and Validation Testing

Unit, integration, and system level software verification testing were performed to demonstrate the efficacy of the software and to confirm operation of the machine. The following testing was performed:

- Functional and Performance Verification
- Regression Testing
- Code Reviews

Software verification information within this submission is provided in accordance with the following FDA guidance documents:

- *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (11 May 2005)
- *Guidance for Off-The-Shelf Software Use in Medical Devices* (27 September 2019)
- *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* (02 October 2014)

5.9.8. Animal Studies

No animal studies were performed on the devices.

5.9.9. Clinical Studies

Clinical studies were not performed on the devices. However, an evaluation of published literature on the use of the predecessor device that is currently available outside of the U.S. was conducted.

5.10. Conclusion

The Indications for Use, technological characteristics, design, and performance requirements of the 5008X Hemodialysis System and its components are substantially equivalent to those of the predicate and secondary predicate devices. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the 5008X Hemodialysis System and all components included in this submission are safe and effective for their intended use.