December 16, 2022

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

Re: K220281
Trade/Device Name: multiFiltratePRO System
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI
Dated: January 31, 2022
Received: February 1, 2022

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Jade M. Noble -S

For
Gema Gonzalez
Acting 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)*

K220281

Device Name
multiFiltratePRO System

Indications for Use *(Describe)*

The multiFiltratePRO System is indicated for the following use: Continuous Renal Replacement Therapy (CRRT) for patients weighing 40 kilograms or more with acute renal failure with or without fluid overload.

All treatments administered by the multiFiltratePRO System must be prescribed by a physician.

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, Senior Director
Preparation Date:	31 January 2022

5.2. Device Name

Trade Name:	multiFiltratePRO System
Common Name:	Dialyzer, High Permeability With or Without Sealed Dialysate System
Regulation Name:	High Permeability Hemodialysis System
Regulatory Class:	Class II per 21 CFR § 876.5860
Product Code:	KDI
Product Code Name:	Dialyzer, High Permeability With or Without Sealed Dialysate System
FDA Review Panel:	Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

The predicate device for the multiFiltratePRO System is the PrisMax cleared under K163530. The predicate device for the multiFiltratePRO Hemodiafiltration (HDF) Cassette is the Prismaflex HF 1000 Set and HF 1400 Set cleared under K042938.

Neither of the predicate devices has been subject to an open design-related recall.

5.4. Device Description

5.4.1. Device Identification:

The multiFiltratePRO System (hereinafter referred to as the "mFTPRO System") is designed to provide Continuous Renal Replacement Therapy (CRRT) dialysis.

The mFTPRO System consists of the following components:

- mFTPRO Machine
- mFTPRO HDF Cassette
- mFTPRO Accessories

- multiEffluent Bag, 10 L
- Adapter Hemofiltration (HF) Female – Luer Lock Male
- Hemofiltration (HF) Female – Spike Adapter
- Pressure Line for MTS (Medizin Tecknik Schweinfurt)
- Vented Spike

5.4.2. Device Characteristics

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

The mFTPRO HDF Cassette is single-use, ethylene oxide (EO) sterilized tubing cassette.

5.4.3. Environment of Use

The mFTPRO System is intended to be used in healthcare facilities.

5.4.4. Brief Written Description of the Device

The mFTPRO System provides CRRT dialysis. The following CRRT modalities will be available with the mFTPRO System:

- CVVHD – Continuous Veno Venous Hemodialysis
- CVVH – Continuous Veno Venous Hemofiltration, with pre-dialyzer dilution, post-dialyzer dilution, and pre-post-dialyzer dilution
- CVVHDF – Continuous Veno Venous Hemodiafiltration, with both pre-dialyzer dilution and post-dialyzer dilution

A high-resolution touchscreen monitor and four (4) operating buttons allow the user to view, monitor, input, and change parameters to manage the treatment on the mFTPRO Machine. In the extracorporeal blood circuit, blood is pumped from the patient through a dialyzer attached to the tubing cassette and back to the patient. Blood, filtrate, dialysate, substitution fluid, and heparin pumps are used as indicated to meet individual patient needs and various therapy modes. Integrated heaters can be used to heat the dialysate and/or substitution fluids as necessary.

The mFTPRO HDF Cassette is indicated for use with the mFTPRO System and can be used for the following CRRT treatment modes: CVVHD, CVVH, and CVVHDF. The cassette is part of the extracorporeal circuit. During treatment, the extracorporeal circuit transports blood from the patient's venous access (e.g., double or two (2) single lumen venous catheters) through a hemodialyzer and back to the patient's venous access.

Anticoagulation of the patient's blood is accomplished by systemic heparin anticoagulation via an integrated heparin pump. This pump can also be used to administer a bolus when required. An infusion line for anticoagulation is included in the cassette.

5.4.5. Materials of Use

The mFTPRO HDF Cassette is classified as externally communicating, circulating blood, prolonged contact (> 24 hours to 30 days) duration, Class II (Category B) device in accordance with FDA guidance *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 cassette components are listed in Table 1.

Table 1: Cassette Materials

Component	Material
Tubing and Components	Polyvinylchloride (PVC) Terephthalate Glycol Polypropylene (PP) Acrylonitrile Butadiene Styrene (ABS) High density Polyethylene Polycarbonate (PC) Polyamide Silicone Polybutylene Terephthalate Polytetrafluoroethylene Polyisoprene Thermoplastic Elastomer Polystyrene Pentaerythritol Triacrylate
Bonding Solvent	TetraMEK (95% Tetrahydrofuran/5% MEK)

5.4.6. Key Performance Specifications/Characteristic

The key performance specifications and characteristics for the mFTPRO System (mFTPRO Machine and mFTPRO HDF Cassette) are outlined in Table 2.

Table 2: Key Performance Specifications/Characteristics

Feature	Specification/Characteristic
mFTPRO Machine	
Blood Flow Rate	Range: 10–500 mL/min Increment: 10 mL/min
Dialysate Flow Rate	**CVVHD, CVVHDF** Range: 600–4800 mL/hr Increment: 10 mL/hr

Table 2: Key Performance Specifications/Characteristics

Feature	Specification/Characteristic
Replacement Solution/Substitution Fluid Flow Rate	**CVVH, CVVHDF** Range: 600–4800 mL/hr Increment: 10 mL/hr
Patient Fluid Removal Performance (Range)	0–990 mL/hr Increment: 10 mL/hr
mFTPRO HDF Cassette	
Maximum Blood Flow Rate	500 mL/min
Minimum Arterial (Access) Pressure	-300 mmHg
Maximum Venous (Return) Pressure	500 mmHg
Blood Pump Segment [Inner/Outer Diameter (ID/OD)]	6.4 mm (ID), 10.0 mm (OD)

5.5. Indications for Use

The multiFiltratePRO System is indicated for the following use: Continuous Renal Replacement Therapy (CRRT) for patients weighing 40 kilograms or more with acute renal failure with or without fluid overload.

All treatments administered by the multiFiltratePRO System must be prescribed by a physician.

5.6. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the mFTPRO System and its components (i.e., mFTPRO HDF Cassette) are substantially equivalent to the primary predicate device PrisMax (K163530) and secondary predicate Prismaflex HF 1000 Set/HF 1400 Set (K042938):

- Indications for Use
- Technological Characteristics
- Anticoagulation Method
- Therapy Modes

5.7. Sterilization Testing (Cassette)

The mFTPRO HDF Cassette is sterilized by exposure to EO. The sterility assurance level (SAL) is 10^{-6}. Sterility and non-pyrogenicity are claimed for the fluid pathway of the cassette.

5.7.1.1. 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 mFTPRO HDF Cassette.

5.7.1.2. Bacterial Endotoxin (Pyrogenicity) Testing

The mFTPRO HDF Cassette was tested for bacterial endotoxin (pyrogenicity) with Limulus Amebocyte Lysate (LAL) and determined to be non-pyrogenic (< 20 EU/device) using principles of *ANSI/AAMI/ST72:2019 Bacterial Endotoxins – Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing*.

5.7.1.3. Sterile Barrier Testing

Sterility of the mFTPRO HDF Cassette is maintained by the Tyvek porous packaging bag (pouch). The package integrity tests were performed on the mFTPRO HDF Cassette packaging. Test selections included, but were not limited to, the application of principles established by ISO 11607-1. Based on the results, FMCRTG concludes that the product and package integrity and sterility of the mFTPRO HDF Cassette is maintained for its intended shelf life.

5.8. Performance Data

5.8.1. mFTPRO Machine Performance Testing Summary

The following performance tests were conducted on the mFTPRO Machine to support the determination of substantial equivalence:

- Software Verification and Validation
- Functional Design Verification
- Electrical Safety and Electromagnetic Compatibility (EMC)
- Essential Performance
- Simulated Shipping and Distribution

All testing met predetermined acceptance criteria.

5.8.2. mFTPRO HDF Cassette Performance Testing Summary

Testing conducted to support the determination of substantial equivalence for the mFTPRO HDF Cassette is summarized in Table 3.

Table 3: mFTPRO HDF Cassette Performance Testing Summary

Test Conducted	Test Objective
Structural Integrity	Demonstrate that the bloodlines can withstand 1.5X the labeled maximum positive and negative pressures
Connectors to Hemodialyzers, Hemodiafilters, or Hemofilters (Compatibility)	Verify that the design of the connectors is in compliance with ISO 8637:2010 and ISO 8638:2010, and is compatible with the blood dialyzer ports

Table 3: mFTPRO HDF Cassette Performance Testing Summary

Test Conducted	Test Objective
Connectors to Vascular Access Devices (Compatibility)	Verify that the design of the blood patient connectors of the Arterial and Venous lines is in compliance with ISO 80369-7 and is compatible with Arterial line to the blood inlet access of the patient and the Venous line to the blood return access of the patient
Connectors to Ancillary Components (Compatibility)	Demonstrate that the connectors to ancillary components meet ISO 80369-7 requirements
Color Coding	Demonstrate that the color-coded components meet the requirements of ISO 8638
Access Ports	Demonstrate that the injection ports can withstand 1.5X the manufacturer's recommended maximum positive and negative pressures after multiple accesses
Blood Pathway Volume	Specify the blood pathway volume of the subject device (arterial and venous lines)
Air-Capture Chamber Fill Level	Verify the instructions related to the recommended fill level of the air-capture chambers are included in the Instructions for Use (IFU)
Transducer Protectors (TPs)	Verify the TP can maintain a secure and leak-free connection to the hemodialysis machine when subjected to pressures 1.5X the manufacturer's maximum pressure
Pump Segment Performance	Verify the actual blood pump segment flow rate over 72 hours
Tubing Compliance	Verify that the tubing is capable of being occlusively clamped by the venous line clamp of the hemodialysis machine at 1.5X the recommended maximum pressure
Endurance Tests	Verify that the device can withstand maximum labeled flow rate (500 mL/min) and maximum pressure (-300 and 500 mmHg) for 63 hours, which is equivalent to the runtime for the maximum labeled volume
Tensile Testing (Gluing Strength Connection Test)	Verify that the resistance load of the gluing between tubes and components is above 50%. With respect to the stress resistance (daN) of the type of tube or above the force resulting from the analysis done, consider the mass of the tubing set filled with blood, the force identified at the interface between the pump tube and the machine pump, and studies performed on specific components.
Burst Test	Demonstrate resistance of the packaging to 1.5X the maximum labeled pressure
Dye Penetration	Verify that there is no channel in the packaging to allow dye penetration per ASTM F1929
Seal Strength	Verify that the seal strength of the packaging is ≥ 3 N per ASTM F88

Table 3: mFTPRO HDF Cassette Performance Testing Summary

Test Conducted	Test Objective
Visual Inspection for Packaging (Shipping Study)	Demonstrate that shipping case, packaging configuration, and palletization pattern maintain the product's structural integrity during manual handling and motorized freight

5.8.3. Biocompatibility Testing

Biocompatibility testing for the mFTPRO System patient-contacting components was conducted in accordance with ISO 10993-1:2018 and FDA guidance *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 mFTPRO HDF Cassette:

- Cytotoxicity, ISO MEM Elution
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Material-Mediated Pyrogenicity
- Systemic Toxicity, Acute
- Systemic Toxicity, Subchronic
- Genotoxicity, Gene Mutation
- Genotoxicity, Chromosome Aberration
- Hemocompatibility, ASTM Hemolysis (Direct)
- Hemocompatibility, *In Vitro* Thrombosis
- Hemocompatibility, Prothrombin Time
- Hemocompatibility, Platelet Count
- Hemocompatibility, Leukocyte Count
- Hemocompatibility, Complement 3a
- Chemical Characterization

A Toxicological Risk Assessment was also performed.

5.8.4. Human Factors Validation Testing

The mFTPRO System was validated for safe and effective use in accordance with FDA guidance *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016).

5.8.5. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety testing for the mFTPRO Machine was conducted in accordance with *ANSI/AAMI ES 60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).*

EMC for the mFTPRO Machine was performed in accordance with *IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.*

5.8.6. 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 device. 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)

5.8.7. Animal Studies

No animal studies were conducted.

5.8.8. Clinical Studies

No clinical studies were conducted.

5.9. Conclusion

The information provided in this submission, including design verification, risk management, electrical safety, EMC, biocompatibility, and usability testing, demonstrates the mFTPRO System functions as intended and supports the determination of substantial equivalence to the predicate devices. Test results demonstrate that the differences between the proposed and the predicate devices do not raise any new concerns with regard to safety or effectiveness.

The Indications for Use, technological characteristics, design, and performance of the mFTPRO System are substantially equivalent to those of the predicate devices. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the mFTPRO System is safe and effective for its intended use.