May 13, 2022

Nephros, Inc.
Vashone R. Thomas
VP of QA/RA
380 Lackawanna Place
South Orange, New Jersey 07079

Re: K210575
Trade/Device Name: HDF Assist Mudule, HDF Infusion Set and Substitution Filter
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: April 7, 2022
Received: April 13, 2022

Dear Vashone Thomas:

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,

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)*
K210575

Device Name
HDF Assist Module
HDF Infusion Set & Substitution Filter

Indications for Use *(Describe)*
The HDF Assist Module is indicated for use, with the Fresenius 2008K, 2008K2, and 2008T dialysis machines, for treatment of adult patients with acute or chronic renal failure or whenever hemodiafiltration is prescribed by a physician.

The HDF Assist Module works in conjunction with a qualified host high permeability (UF controlled) hemodialysis machine and its accessories (i.e., bloodlines, dialysate, concentrates, etc.), the HDF Assist Module accessories (HDF Infusion Set and Substitution Filter), appropriately purified water and ultrapure dialysate for hemodialysis, and a high permeability hemodialyzer / hemodiafilter (i.e., the OLPūr™ MD 220 Hemodiafilter).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Office of Chief Information Officer
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Company: Nephros, Inc.
Type of Submission: Traditional 510(k) Premarket Notification
Device Name: HDF Assist Module

5. SECTION 05: 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 Part 807.92.

Submitter's Information:

Submitter' Name & Company Address:	Nephros Inc. 380 Lackawanna Place South Orange, NJ 07079 Establishment Registration # 3003337893
Contact Person:	Vashone R. Thomas; Vice President of Quality and Regulatory Affairs 380 Lackawanna Place South Orange, NJ 07079
Phone:	201-345-0829
Facsimile:	201-343-5207
Email:	vashone@nephros.com
Date Prepared:	May 13, 2022

Device Information:

Trade Name:	HDF Assist Module, HDF Infusion Set & Substitution Filter
Regulation Name:	High Permeability Hemodialysis System
Classification Number:	Class II per 21 CFR Part 876.5860
Product Code	KDI
Classification Panel	Gastroenterology/Urology

Predicate Information:
The predicate device for the HDF Assist Module is the OLPūr™ H2H Hemodiafiltration Module, K112314, granted 04/27/2012.

Device Description:
The HDF Assist Module is a software controlled; electro-mechanical medical device designed to work in combination with a sterile single use HDF Infusion Set (an accessory included in this submission) and a qualified host high permeability (UF controlled) hemodialysis machine, which produces ultrapure dialysis fluid. Upon installation the HDF Assist Module is connected to the host dialysis machine's IV Pole and plugged into a Standard 120VAC electrical mains power source.

To perform a hemodiafiltration treatment with the HDF Assist Module, the device is used in unison with the accessory sterile, single-use HDF Infusion Set to generate and control the online substitution fluid for hemodiafiltration from the ultrapure dialysis fluid of the host dialysis machine. The sterile HDF Infusion Set consists of an 0.25 m^2 ultrafilter, tubing including a peristatic pump segment, pressure sensor pods, and check valves.

The HDF Infusion Set is primed prior to treatment to remove air from the Set. The HDF Infusion Set is placed on the unit in preparation for each HDF treatment. A peristatic pump in the HDF Assist Module pumps a preset amount of ultrapure dialysis fluid produced by the host dialysis machine via the peristatic pump segment in the HDF Infusion Set. The dialysis fluid is drawn from an input dialysate Hansen T-connector and pumped through a sterile

single use 0.25 m^2 ultrafilter in the HDF Infusion Set. The rest of the dialysis fluid flows outside of the fiber in the OLPūr™ MD 220 Hemodiafilter as in conventional hemodialysis.

During priming and treatment, the ultrafilter in the HDF Infusion Set removes bacteria and endotoxins from the ultrapure dialysis fluid, thereby generating an injectable quality substitution (replacement) fluid of correct electrolyte composition. The ultrafiltered substitution fluid flows through tubing connected to the extracorporeal circuit where it is infused as part of the hemodiafiltration treatment at the MD220 Mid-Dilution port. The ultrafilter is 100% tested in a production integrity check during manufacture.

Indications for Use:

	Predicate OLPūr™ H2H Hemodiafiltration (HDF) Module	**Modified Device** HDF Assist Module, HDF Infusion Set & Substitution Filter
Indications for Use:	The OLPūr™ H2H Hemodiafiltration (HDF) Module is indicated for use, with an approved dialysis machine, for treatment of patients with acute or chronic renal failure or whenever hemodiafiltration is prescribed by a physician. The OLPūr™ H2H Hemodiafiltration (HDF) Module works in conjunction with a qualified host high permeability (UF controlled) hemodialysis machine and it's accessories (i.e., bloodlines, dialysate, concentrates, etc.), the H2H Module accessories (water and substitution fluid filters infusion / rinse line, and optional blood extension line), appropriately purified water for hemodialysis, and a high permeability hemodialyzer / hemodiafilter (i.e., the OLPūr™ MD 220 Hemodiafilter).	The HDF Assist Module is indicated for use, with the Fresenius 2008K, 2008K2, and 2008T dialysis machines, for treatment of adult patients with acute or chronic renal failure or whenever hemodiafiltration is prescribed by a physician. The HDF Assist Module works in conjunction with a qualified host high permeability (UF controlled) hemodialysis machine and its accessories (i.e., bloodlines, dialysate, concentrates, etc.), the HDF Assist Module accessories (HDF Infusion Set and Substitution Filter), appropriately purified water and ultrapure dialysate for hemodialysis, and a high permeability hemodialyzer / hemodiafilter (i.e., the OLPūr™ MD 220 Hemodiafilter).

Summary and Comparison of Technological Characteristics with Predicate Device:

The proposed HDF Assist Module and the predicate device (K112314) are substantially equivalent in the following technological characteristics:

- Design Features
- Electrical Safety
- Electromagnetic Compatibility (EMC)
- Material Biocompatibility (Patient and Non-Patient Contact)
- Microbiological Quality (maximum allowable levels for total viable microbial count and endotoxins in the substitution fluid)
- Principle of Operation
- Software
- Standards (Electrical and electromagnetic safety, Water Purification and Hemodialysis Standards)

The performance testing completed on the proposed device to support the determination of substantial equivalence is summarized below and has been developed in accordance with appropriate FDA guidance

documents and relevant standards. The HDF Assist Module has been modified to simplify the design and optimize performance.

The complete list of changes implemented and included in the HDF Assist Module are included in the summary of Non-clinical Performance data below.

Assessment of Non-Clinical Performance Data/Substantial Equivalence:

Safety and Effectiveness

To assess the effects of the modified characteristics of the modified device and to demonstrate substantial equivalence with the predicate device, the following data assessed by scientific methods, performance and clinical data are provided.

Biocompatibility Testing

Design updates to the module, infusion set, and substitution filter have been made to the predicate device and biocompatibility has been evaluated. Testing was performed according to ISO 10993-1, ISO 10993-4, ISO 10993-5, ISO 10993-10, ISO 10993-11 and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1", under the category of Externally Communicating Device; Blood Path, indirect; Prolonged (Category B).

Electrical Safety

The HDF Assist Module has been evaluated against the requirements of FDA Consensus and International Standards for Electrical Safety and other applicable standards by an independent ANSI Certified Testing Service company Interek Testing Services N.A. Inc. The applicable standards include:

- AAMI ES60601-1:2005 +A1 – Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- CSA C22.2#60601-1:2014 Ed.3 – Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-8 Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems [IEC 60601-1-8:2003 Ed.1+A1]
- IEC 60601-2-16:2018 - Medical electrical equipment Part 2-16: Particular requirements for the safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment (Applicable Clauses)

Electromagnetic Compatibility (EMC)

The HDF Assist Module has been evaluated against the requirements of FDA Consensus and International Standards for EMC Compatibility by an independent ANSI Certified Testing Service company (Interek Testing Services N.A. Inc.) The applicable standards include:

- IEC 60601-1-2 ed 4.0 (2014-02) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests (with EMC deviations per IEC 60601-2-16:2018)

Microbiological Quality

The microbiological quality of the substitution fluid as determined by the maximum allowable levels for total viable microbial count and endotoxins is in conformance with ANSI AAMI ISO 23500:2014 Guidance for the preparation and quality management of fluids for hemodialysis and related therapies. The microbiological

quality of the substitution fluid produced by the HDF Assist Module is assured by a multistage redundant system.

1. As required for standard hemodialysis, there must be a properly maintained dialysis water treatment system with reverse osmosis and other required components as determined by water analysis and the ISO 23500 standard. This produces maximum allowable levels for total viable microbial count and endotoxins in the water input to the dialysis machine of <100 CFU/ml and <0.25 EU/ml, with an action limit half the maximum value (<50 CFU/ml and <0.125 EU/ml).
2. The qualified host Fresenius 2008 K, 2008K2, and 2008T Dialysis Machines must be equipped with the Diasafe® (K944767) or Diasafe®plus Options (K182367) which, provide ultrapure dialysis fluid in conformance with ISO 23500:2014 of <0.1 CFU/ml and <0.03 EU/ml. Note the qualified Fresenius machines with Diasafe®/Diasafe®*plus* are indicated to provide this maximum level of bacteria and endotoxins, when presented with input dialysis solution with a bacterial two times the maximum level and an endotoxins level of 8 times the maximum level per ISO 23500 standard for dialysis water.
    a. In addition, the integrity of the Diasafe®/Diasafe®*plus* filters are tested after each chemical disinfection by the Fresenius 2008 K, 2008K2, and 2008T Dialysis Machine.
    b. The sterile single use Nephros HDF Infusion set contains an additional filtration step using a 0.25 m^2 ultrafilter as required by the ISO 23500 Standard and FDA Guidance for the Content of Premarket Notifications for Hemodialysis Delivery Systems. Both the membrane and filter integrity are 100% tested in the production process and the filter is capable of a Log 10^5 reduction endotoxins and a Log 10^{11} reduction of bacteria. Since this redundant filtration step is a single use disposable, there is no potential for biofilm formation in quiescent periods in between treatments. Note the integrity of the D150/U filter is 100% checked during the production process, in an identical process to dialyzer integrity process.

Software Verification and Validation Testing

For all software development and modifications, system level software verification testing per ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)] demonstrated that the HDF Assist Module meets functional and performance software requirements per ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]

System Performance Testing

Performance Testing included verification of design inputs specific to HDF Assist Module including HDF Infusion Set in the following areas:

- Ultrafilter Disinfection and Reprocessing System Removal
- Internal Pump Removal
- Software Modification
- Module Modification
- Stand Removal
- Filter and Cap Modification
- Infusion Set and Substitution Filter Modification
- Sensor and Regulator Modification

Usability Testing

The HDF Assist Module has been evaluated against the requirements of FDA Consensus and International Standards for Usability

- IEC 60601-1-6-Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability [IEC 60601-1-6:2010 Ed.3 +A1]

Animal Studies

Not applicable. No animal studies were performed in support of the modifications.

Clinical Studies

Not applicable. No clinical studies were performed in support of the modifications.

Comparison of Substantial Equivalence

The predicate device, OLPūr™ H2H Hemodiafiltration (HDF) Module (K112314) was used for modification to the HDF Assist Module. The modified device has a substantially equivalent indication for use as the cleared and marketed predicate device. HDF Assist Device modifications are due to the removal of the secondary function of the predicate, as a reprocessing machine, that disinfects the H2H Substitution Filter. The HDF Infusion set including 0.25 m^2 ultrafilter is a sterile, single use medical device, so there is no need for an ultrafilter reprocessing capability. The 0.25 m^2 ultrafilter in the HDF Infusion set uses the same membrane and has similar technological characteristics of bacteria and endotoxins removal to the predicate device. These modified characteristics are achieved by a validated process that demonstrates safety and effectiveness of the modified device.

Conclusion

The successful non-clinical testing indicated above demonstrates the safety and effectiveness of the HDF Assist Module when used for the defined indications for use and intended use. The information and data provided in this Special 510(k) Premarket Notification establishes that the modified HDF Assist Module is substantially equivalent in the intended use, indications for use, design, principle of operation, technology, materials, specifications, and performance to the original referenced OLpūr™ H2H Hemodiafiltration (HDF) Module.