510(k) Summary: Nephros OLpūr® H_2H Hemodiafiltration (HDF) Module and OLpūr MD 220 Hemodiafilter

Submitter:	Nephros Inc. 41 Grand Ave, Suite 201 River Edge, NJ 07661 Establishment Registration # 3003337893
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Date Prepared	August 10, 2011
Trade Name	Nephros OLpūr H_2H Hemodiafiltration (HDF) Module and OLpūr MD 220 Hemodiafilter
Proposed Class	Class II
Classification Name and Number	21 CFR Part 876.5665 Water Purification System for Hemodialysis; 21 CFR Part 876.5860 Dialyzer, High Permeability With or Without Sealed Dialysate System
Product Code	FIP, KDI
Predicate Devices	➢ Predicate for the Nephros MD 220 Hemodiafilter - Nephros OLpūr HD190 (K050603) ➢ Predicate for the H_2H Module with qualified UF-Controlled Hemodialysis Machine - Aksys PHD Personal Hemodialysis System (K010131) ➢ Predicate for the H_2H Module in the stand-alone configuration - Aksys PHD Personal Hemodialysis System (K010131) ➢ Predicates for the H_2H Substitution Fluid Filter – Nephros DSU Dual Stage Ultrafilter (K090885), Minntech

	Renaguard Dialysate Filter (K945136), Gambro Diaclear Ultrafilter (K003957), Fresenius Citric Acid Dialyzer Reprocessing (K974090) ➢ Predicates for the H_2H Water Filter - Nephros DSU Dual Stage Ultrafilter (K090885), Minntech FiberFlo Hollow Fiber Capsule Water Filter (K983126) ➢ Predicates for the Disposable H_2H Infusion Line and Blood Tubing Extension Set - Codan IV Administration Sets (K033301), Nipro Blood Tubing Set w/Transducer Protector and Priming Set (K072024)
Device Description	The H_2H™ Hemodiafiltration Module is a programmable electro-mechanical medical device designed to work in conjunction with and in close proximity to a hemodialysis machine during patient treatments. Upon installation, the H_2H Module is placed next to the hemodialysis machine (which can be on either side depending upon type and model of the hemodialysis machine) and is connected to the clinic's water supply, drain, and electricity. The H_2H Hemodiafiltration Module serves two basic functions. The Module's primary function is to generate on-line substitution fluid for hemodiafiltration. The H_2H Module does this by ultrafiltering dialysate, provided by the hemodialysis machine, through a reusable substitution filter. The secondary function of the H_2H Hemodiafiltration Module is to serve as a substitution filter reprocessing machine. These steps are performed when the H_2H Hemodiafiltration Module is not connected to the hemodialysis machine. More detailed descriptions of the device, its accessories and how the system functions can be found in Section 11 (Device Description) of this submission.

Intended Use	The OLpūr H_2H Hemodiafiltration (HDF) Module is indicated for use, with a UF controlled hemodialysis machine that provides ultrapure dialysate in accordance with current ANSI/AAMI/ISO standards, for treatment of patients with chronic renal failure as prescribed by a physician. The OLpūr MD 220 Hemodiafilter is indicated for use for hemodiafiltration of patients with chronic renal failure. The OLPūr MD 220 Hemodiafilter is only to be used with the OLpūr H_2H Hemodiafiltration Module. Selection of patients, as well as treatment operating parameters, are a medical decision and the responsibility of the prescribing physician. The OLpūr H_2H Hemodiafiltration (HDF) Module works in conjunction with a qualified host (UF controlled) hemodialysis machine and it's accessories (i.e., bloodlines, dialysate, concentrates, etc.), the H_2H Module accessories (water and substitution fluid filters, infusion / rinse line, and optional blood extension line), appropriately prepared water and ultrapure dialysate for hemodialysis, and a high permeability hemodiafilter (i.e., the OLPūr MD 220 Hemodiafilter).
Summary of the Technological Characteristics	The proposed device has the same technological characteristics and is similar in design as compared to the predicate devices and already approved kidney dialysis therapy.
Assessment of Non-clinical Performance Data / Substantial Equivalence	Refer to Section 18 of this application for Bench Analyses performed on the subject devices. Refer to Section 20 of this application for clinical data supporting substantial equivalence of the subject system as compared to approved high flux dialysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 27 2012

Greg Collins, Ph.D.
V.P. of R&D
Nephros, Inc.
41 Grand Ave.
RIVER EDGE NJ 07661

Re: K112314
Trade/Device Name: Nephros OLPūr® H_2H Hemodiafiltration (HDF) Module and OLPūr MD 220 Hemodiafilter
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: April 26, 2012
Received: April 27, 2012

Dear Dr. Collins:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K_112314**

Device Name: Nephros OLPūr® H2H Hemodiafiltration (HDF) Module and OLPūr MD 220 Hemodiafilter

Indications For Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112314