DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 2, 2017

Nephros, Inc.
Hollie Johnson
Director Quality and Requlatory
41 Grand Ave
River Edge, NJ 07661

Re: K161304
Trade/Device Name: EndoPur Endotoxin 10" Filter Flat
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System For Hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: December 23, 2016
Received: December 27, 2016

Dear Hollie Johnson:

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)*
K161304

Device Name
EndoPur Endotoxin 10" Filter Flat

Indications for Use *(Describe)*

INDICATIONS FOR USE
Indications for Use: The EndoPur Endotoxin 10" Filter Flat is intended to be used to filter water used in hemodialysis devices. It assists in providing hemodialysis quality water. The device is not a complete water treatment system, but serves to remove biological contaminants. Therefore it must be used in conjunction with other water treatment equipment (Reverse Osmosis, Deionization, etc.).

CONTRAINDICATIONS
Heat sterilization is contraindicated for use with polypropylene housings that are not rated for disinfection temperatures above 80°C

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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Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: EndoPur Endotoxin 10” Filter Flat

Submitter:	Nephros Inc. 41 Grand Ave River Edge, NJ 07661 Establishment Registration # 3003337893
Contact Person	Hollie Johnson ; Director of Quality and Regulatory 41 Grand Ave River Edge, NJ 07661 201-343-5202 x101(p) 201-343-5207 (f) hollie@nephros.com
Date Prepared	December 28, 2016
Trade Name	EndoPur Endotoxin 10” Filter Flat
Proposed Class	Class II
Classification Name and Number	21 CFR Part 876.5665 Water Purification System for Hemodialysis
Product Code	FIP
Predicate Devices	FiberFlo™ Hollow Fiber Cartridge Water Filters – K95439
Device Description	The EndoPur Endotoxin 10” Filter Flat is a hollow fiber ultrafilter that retains bacteria, viruses, endotoxin and particulate from water used in hemodialysis.
Intended Use	The EndoPur Endotoxin 10” Filter Flat is a hollow fiber ultrafilter that retains bacteria and endotoxin from fluid.
Indications For Use	The EndoPur Endotoxin 10” Filter Flat is intended to be used to filter water used in hemodialysis devices. It assists in providing hemodialysis quality water. The device is not a complete water treatment system, but serves to remove biological contaminants. Therefore it must be used in conjunction with

	other water treatment equipment (Reverse Osmosis, Deionization, etc.). CONTRAINDICATIONS Heat sterilization is contraindicated for use with polypropylene housings that are not rated for disinfection temperatures above 80°C
Summary of the Technological Characteristics	The subject device has the same technological characteristics and is similar in design as compared to the primary and reference devices; see executive summary located in section 10.
Assessment of Non-clinical Performance Data / Substantial Equivalence	The EndoPur Endotoxin 10” Filter Flat has been tested for performance. The tests conducted include Flow Rate versus Pressure Drop, Pyrogen Removal, Virus Challenge Test, Bacteria Challenge Test and Disinfection Compatibility. This filter was found to be substantially equivalent to the primary predicate Minntech Fiberflo Filter (K954349) and reference device, DSU/SSU.
Biocompatibility Testing	Exhaustive Extractable and Leach testing was performed, evaluated by a toxicologist and found to be safe. AAMI panel was executed using ANSI/AAMI 13959 Water for Hemodialysis and Related Therapies to determine residual levels after each disinfection process on accelerated aged product. All results were found to be acceptable.
Electrical Safety and Electromagnetic Compatibility (EMC)	Not Applicable; not and Active Medical Device
Software Verification and Validation Testing	Not Applicable; No Software contained
Mechanical and Acoustic Study	Not Applicable

Animal Study	Not Applicable
Clinical Studies	Not Applicable
Conclusions	Since the predicate device is comprised of the same materials of construction that have no adverse events while on the market and the safety testing completed by Nephros demonstrates no toxicity concerns, Nephros EndoPur Endotoxin 10” filter Flat is ready for marketing for its intended use, which is the same as its predicate and reference devices.