



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

April 8, 2016

Nephros, Inc.
James Summerton
Director Product Development
41 Grand Ave
River Edge, NJ 07661

Re: K153084
Trade/Device Name: S100 Point of Use Filter
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System for Hemodialysis
Regulatory Class: II
Product Code: NHV
Dated: March 7, 2016
Received: March 10, 2016

Dear James Summerton,

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,

Joyce M. Whang -S

for 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): K153084

Device Name: S100 Point of Use Filter

Indications For Use:

The S100 Point of Use Filter is intended to be used to filter EPA quality drinking water. The filter retains bacteria. By retaining bacteria in water for washing and drinking, the filter may aid in infection control. The filter produces water that is suitable for cleaning of equipment used in medical procedures and washing of surgeon's hands. The filter is not intended to provide water that can be used as a substitute for USP sterile water.

Prescription Use

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary: S100 Point of Use Filter

Submitter:	Nephros Inc. 41 Grand Ave River Edge, NJ 07661 Establishment Registration # 3003337893
Contact Person	Jim Summerton, Director Product Development 41 Grand Ave River Edge, NJ 07661 201-343-5202 (p) 201-343-5207 (f) summerton@nephros.com
Date Prepared	March 8, 2016
Trade Name	S100 Point of Use Filter
Proposed Class	Class II
Classification Name and Number	21 CFR Part 876.5665 Water Purification Device, General Medical Use
Product Code	NHV
Predicate Device	DSU-H and SSU-H Ultrafilters – K141731
Device Description	The S100 Point of Use Filter is a hollow fiber microfilter that retains bacteria from water used for washing and drinking.
Intended Use	The S100 Point of Use Filter is intended to be used to filter EPA quality drinking water. The filter retains bacteria. By retaining bacteria in water for washing and drinking, the filter may aid in infection control. The filter produces water that is suitable for cleaning of equipment used in medical procedures and washing of surgeon's hands. The filter is not intended to provide water that can be used as a substitute for USP sterile water.
Summary of the Technological	The proposed device contains a polysulfone hollow fiber membrane encased in an ABS housing that retains bacteria.

Characteristics	Removal of contaminants is through size exclusion.
Assessment of Non-clinical Performance Data / Substantial Equivalence	The S100 Point of Use Filter has been tested for performance. The tests conducted include Flow Rate versus Pressure Drop, Simulated Use Life, Bacteria Challenge Test and Biocompatibility. The filters were found to be substantially equivalent to the predicate DSU-H and SSU-H Ultrafilters (K141731).

SUBJECT TO PREDCATE DEVICE COMPARISON TABLE

	Subject Device	Predicate Device
510(k) Number	K153084	K141731
Manufacturer Name	Nephros Inc.	Nephros Inc.
Indications for Use	The S100 Point of Use Filter is intended to be used to filter EPA quality drinking water. The filter retains bacteria. By retaining bacteria in water for washing and drinking, the filter may aid in infection control. The filter produces water that is suitable for cleaning of equipment used in medical procedures and washing of surgeon's hands. The filter is not intended to provide water that can be used as a substitute for USP sterile water.	The DSU-H and SSU-H Ultrafilters are intended to be used to filter EPA quality drinking water. The filters retain bacteria, viruses and endotoxin. By providing ultrapure water for washing and drinking, the filters aid in infection control. The filters produce water that is suitable for wound cleansing, cleaning of equipment used in medical procedures and washing of surgeon's hands. The filters are not intended to provide water that can be used as a substitute for USP sterile water.
Operation		
Feed Water Source	Municipal tap water	Municipal tap water
Use Life	Up to 3 months	Up to 3 Months (SSU-H) Up to 6 Months (DSU-H)
Maximum Inlet Pressure	75 psi	75 psi (SSU-H) 100 psi (DSU-H)
Flow Rate vs. Pressure Drop	4 L/min at 20 psi	4.5 L/min at 20 psi (SSU-H) 4 L/min at 20 psi (DSU-H)

	Subject Device	Predicate Device
Materials		
Casing	ABS	ABS
Filter Element(s)	Polysulfone Microfiltration Hollow Fiber	Polysulfone Ultrafiltration Hollow Fiber
Removal		
Bacteria Reduction	$> 10^9$	$> 10^{11}$
Virus removal	n/a	$> 10^8$
Endotoxin Reduction	n/a	$> 10^5$