



Food and Drug Administration
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Silver Spring, MD 20993-0002

June 10, 2016

Pall International, Sarl
Karen D. Peterson-Doyle
Director, Regulatory Affairs
25 Harbor Park Drive
Port Washington, NY 11050

Re: K153434
Trade/Device Name: Pall-Aquasafe™ Water Filter
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System for Hemodialysis
Regulatory Class: II
Product Code: NHV
Dated: May 2, 2016
Received: May 2, 2016

Dear Karen D. Peterson-Doyle:

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)
K153434

Device Name

Pall-Aquasafe Water Filter

Indications for Use (Describe)

The Pall-Aquasafe Water Filter is intended to be used to filter EPA (Environmental Protection Agency in USA) quality drinking water. By retaining bacteria, the filters may aid in infection control. The filters produce water that is suitable for washing and drinking, superficial wound cleansing (minor cuts, scrapes, or abrasions), 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 grade sterile water.

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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510(k) Summary

As required by 21 CFR 807.92

Pall-Aquasafe™ Water Filter

Administrative Information

Date: April 28, 2016

510(k) Number: K153434

Submitter: Pall International, Sarl
Ave De Tivoli 3
Fribourg, Switzerland 1700

**Establishment
Registration Number:** 3008412416

Contact Person: Karen D. Peterson-Doyle
Pall Corporation
25 Harbor Park Drive,
Port Washington, NY, USA 11050
516.801.9267

Device Identification

Device Name: Pall-Aquasafe™ Water Filter

Common Name: water purification system for general purposes

Device Classification Name: water purification system for general purposes

Classification Product Code: NHV

Device Classification: Class II

Panel: Gastroenterology/Urology

Predicate Devices: DSU-H and SSU-H Ultrafilters, K141731
Mainstream™ Water Purification Device, K012716

Device Description

The Pall-Aquasafe™ Water Filter is supplied sterile and integrity tested. The Supor® membrane within the filter cartridge is rated and validated at 0.2 micron to remove bacteria, protozoa, fungi and particles in the water supply. It is designed to be used for a maximum of one calendar month (31 days) following initial connection. Suspending use does not extend filter life. The Pall-Aquasafe Water Filter is intended to be used within the healthcare environment such as hospitals, nursing homes, health care facilities or clinical settings where immune-compromised patients may be exposed to waterborne microorganisms originating from the water supply.

Substantial Equivalence Discussion

This Premarket Notification submission requests clearance for the Pall-Aquasafe Water Filter. A comparison of the Pall-Aquasafe Water Filter to the predicate devices is provided in the following table.

	Subject Device	Primary Predicate	Reference Device
510(k) Number	K153434	K141731	K012716
Trade Name	Pall-Aquasafe™ Water Filter Models: AQINA, AQ31F1SA, AQ31F1RA, AQF4A	DSU-H and SSU-H Ultrafilters	Mainstream™ Water Purification Device
Manufacturer	Pall Medical	Nephros Inc.	PrisMedical
Indications for Use	The Pall-Aquasafe™ Water Filter is intended to be used to filter EPA (Environmental Protection Agency in USA) quality drinking water. By retaining bacteria, the filters may aid in infection control. The filters produce water that is suitable for washing and drinking, superficial wound cleansing (minor cuts, scrapes, or abrasions), 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 grade 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.	To produce from EPA grade drinking water, sterile purified water to be used within 24 hours of collection that is suitable for: <ul style="list-style-type: none"> - Cleaning and rinsing open wounds - Infection control (cleaning equipment used in medical procedures, medical personnel's hands) - Use as a diluent for enteral, nutritional, oral vaccine, or oral drug preparations - All other uses of sterile purified water the practitioner or clinician deems necessary - Not for parenteral administration

Device Description	Sterilizing grade 0.2 µm Supor® membrane filtration with integral pre-filter that retains bacteria from water through size exclusion.	Polysulfone 5 nm hollow fiber membrane ultrafilters encased in an ABS housing that retains bacteria, viruses, endotoxin and particulate from water through size exclusion.	Single-use sheet membrane device providing USP Sterile Purified Water through the processes of prefiltration, depth filtration, deionization and sterilizing membrane filtration.
Materials			
Casing	polybutylene terephthalate (PBT)	ABS	Polycarbonate
Filter Element(s)	0.2 µm Supor® (polyethersulfone) membrane filtration with integral pre-filter	5 nm Polysulfone Ultrafiltration Hollow Fiber	Ultrafiltration Sheet Membrane, Polypropylene mesh, Activated Carbon, Deionization Resin Beads
Operation			
Feed Water Source	In-line plumbing	In-line plumbing	Gravity feed
Use Life	31 days	up to 3 Mo. (SSU-H) up to 6 Mo. (DSU-H)	Single-use, 3 Liters
Maximum Inlet Pressure	75 psi @ 140 °F	75 psi (SSU-H) 100 psi (DSU-H)	< 10 psi
Flow Rate and Pressure Drop	Per individual model specification	Unknown	30 ml/min at 5 psi
Filter Retention			
Bacteria Reduction*	> 10 ⁷ CFU/cm ² > 10 ¹⁰ CFU/device	> 10 ¹¹	> 10 ⁷
Virus Reduction*	N/A	> 10 ⁸	> 10 ⁴
Endotoxin Reduction*	N/A	> 10 ⁵	> 10 ⁴
Organic Reduction	N/A	N/A	TOC reduced to < 1 ppm
Ion Reduction*	N/A	N/A	> 10 ³ dissociable ions
*Bacterial, virus, endotoxin and ion reduction units are not specified for the predicate and reference devices.			

Non-clinical Tests Include

Microbial Retention Verification – Testing designed using ASTM F838-05 and Health Industry Manufacturers Association (HIMA) Guidance for validating 0.2 micron sterilizing grade filters using *Brevundimonas diminuta* at a challenge level of $\geq 1 \times 10^7$ colony forming units (CFU) per cm² of effective filtration area. All analysis membranes were found to be free of the test organism.

Microbial Retention in Intermittent Use – Testing designed to confirm that the Pall-Aquasafe Water Filters retain the microbial challenge organism *Brevundimonas diminuta* during typical intermittent use for a period of 35 days using ASTM F838-05 and Health Industry Manufacturers

Association (HIMA) Guidance for validating 0.2 micron sterilizing grade membranes. All analysis membranes were found to be free of the test organism.

Retention of Fungi – Testing performed to demonstrate that the Pall-Aquasafe Water Filters are capable of retaining fungi during a period of one calendar month (maximum 31 days) using *Aspergillus fumigatus* delivered (Day 1: 1×10^4 CFU; Day 15: 2×10^4 CFU and Day 36: 2.4×10^5 CFU). Plates were incubated for 10 days and then integrity tested. Less than 1 (CFU/500mL) were recovered downstream of the filter.

Maximum Operating Temperature and Pressure Rating – Pall-Aquasafe Water filters were tested for operating at a continuous maximum temperature of 60 °C combined with a maximum inlet pressure of 5 bar. The filters were also tested to withstand 70 °C for a cumulative period of 30 minutes over the life of the filter. Filters were integrity tested and testing demonstrated that the filters maintain their integrity over their simulated service life.

Flow Rate Testing at water pressures of 15, 25, 45, 60 and 75 psi

Shelf Life Testing

The following testing was performed:

Integrity Testing of the Packaging

Bacterial Challenge

Burst Pressure Testing

Three-year real-time Shelf Life Testing

Five-year accelerated aging Shelf Life Testing

All filter capsules tested retained integrity and maintained a safety margin above maximum operating pressure after three and five year real-time storage and five years accelerated aging.

Evaluation of Bacteriostatic Additive

Testing demonstrated that the bacteriostatic additive incorporated within the housing polymer to reduce external microbial contamination by greater than 99.5% after 24 hours contact.

Biocompatibility Testing

Biocompatibility evaluation for the Briostor Transfer/Freezing Bag Set was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing: May 1, 1995, and the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process” as recognized by FDA.

The Pall-Aquasafe Water Filters are categorized as an “External Communicating Device, Breached/compromised surfaces, Contact Duration: Limited Exposure.

The battery of testing include:

L929 MEM Elution - ISO

Kligman Guinea Pig Maximization Test – 2 extracts - ISO

Intracutaneous Injection – 2 extracts - ISO

Systemic Injection Test – 2 extracts - ISO

Rabbit Pyrogen Test - Material Mediated - ISO

Statement of Equivalence

The Pall-Aquasafe™ Water Filter is substantially equivalent to the Nephros Inc. DSU-H and SSU-H Ultrafilters (K141731). When used according to the intended use, the Pall-Aquasafe Water Filter does not raise new questions of safety and effectiveness and is at least as safe and effective as the legally marketed devices.