DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 1, 2017

Pall International Sarl
% Randy J. Prebula
Partner
Hogan Lovells U.S. LLP
555 Thirteenth Street NW
Washington, DC 20004

Re: K163609
Trade/Device Name: Pall® QPoint™ Water Filter Capsule
Regulation Number: 21 CFR 876.5665
Regulation Name: Water Purification System for Hemodialysis
Regulatory Class: II
Product Code: NHV
Dated: May 2, 2017
Received: May 2, 2017

Dear Randy J. Prebula:

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,

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 on last page

510(k) Number *(if known)*

K163609

Device Name

Pall® QPoint™ Water Filter Capsule

Indications for Use *(Describe)*

The Pall® QPoint™ Water Filter Capsule is intended to be used within the healthcare environment such as hospitals, nursing homes, healthcare facilities or clinical setting where immune-compromised patients may be exposed to waterborne microorganisms originating from the water supply.

The Pall® QPoint™ Water Filter Capsule is intended to be used to filter EPA (Environmental Protection Agency in USA) quality drinking water. By retaining bacteria, fungi and protozoa 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 filter is 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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PALL Medical

510(k) Summary

Pall Corporation's QPoint™ Water Filter Capsule

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Date Prepared: June 1, 2017

Proprietary Name of Device: Pall® QPoint™ Water Filter Capsule

Common Name: System, Water Purification, General Medical Use

Classification Regulation: 21 C.F.R. § 876.5665, Water Purification System for Hemodialysis

Regulatory Class: Class II

FDA Product Code: NHV

510(k) Number: K163609

Predicate Device: Pall International Sàrl's Pall-Aquasafe™ Water Filter (K153434)

Intended Use/Indications for Use:

The Pall QPoint™ Water Filter Capsule is intended to be used within the healthcare environment such as hospitals, nursing homes, healthcare facilities or clinical setting where immune-compromised patients may be exposed to waterborne microorganisms originating from the water supply.

The Pall QPoint™ Water Filter Capsule is intended to be used to filter EPA (Environmental Protection Agency in USA) quality drinking water. By retaining bacteria, fungi and protozoa 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 filter is not intended to provide water that can be used as a substitute for USP grade sterile water.

The only difference in the indications for use as compared to the predicate device is that the QPoint™ Water Filter Capsules trap fungi and protozoa in addition to bacteria. However, this difference does not change the mechanism of action of the device or its intended therapeutic use, nor does it raise different questions of safety or effectiveness when the device is used as labeled. Performance data support use of the device as proposed.

Device Description:

The Pall QPoint™ Water Filter Capsule is a disposable filter capsule comprised of polyester, polypropylene, and polyethersulphone. The product is not made with natural rubber latex. The filter does not come into direct contact with patients, but indirect contact occurs as the water flowing through the filter is used by patients and by surgeons operating on patients.

Every device batch is integrity tested prior to release, and the filter capsules are supplied sterile. The Qpoint™ filter is a single-use device, *i.e.*, it should not be removed and then re-used; however, a filter capsule can be used for up to two calendar months (maximum 62 days) following initial connection. A double layer Supor® membrane within the filter capsule is rated and validated at 0.2 µm to remove bacteria, fungi, protozoa and particles in the water supply. The filter membrane also has a high-technology integrated pre-filtration layer to provide extended use with higher dirt capacity for better flow rates.

The Filter Capsule is designed to be used with a fixed reusable Docking Station (*i.e.,* Shower or Faucet Assembly, also called a Filter Capsule holder). The filter capsule must be connected to a docking station in order to be used, but it can be exchanged when required without discarding the holder, which have separate reorder codes. The Docking Station need only be exchanged if obvious functional damage is found (*e.g.,* a leak) or when aesthetic wear leads the user to prfer replacing this component.

Summary of Technological Characteristics:

Both the subject and predicate devices operate based on the principle of size exclusion filtration. As water flows through the filter, microorganisms greater than the pore size of any one of its layers are retained so that they do not proceed forward with the water. The 0.2 micron membrane incorporated within the filter capsule is a sterilizing-grade membrane tested for microbial retention according to ASTM F838-05, and performs the principal filtration function. In addition, the Qpoint™ filter also has a highly asymmetric pre-filtration membrane that contains two layers of pre-filtration media (range of ~30 micron down to ~1 micron). This enhances the retention capability, thereby protecting and extending the life of the 0.2 micron membrane.

The main technological differences between the QPoint™ Water Filter Capsule and the predicate device are:

- Subject device has two layers of pre-filter media to allow for greater filtration capacity;
- Subject device has a slightly larger effective filtration area;

- Subject device can be used for a longer duration than the predicate;
- Subject device is designed for use with reusable docking station that also connects to plumbing supply, as opposed to predicate's quick connector adapter;
- Subject device has higher capacity with respect to maximum operating temperature; and
- Subject device is expected to have a longer shelf life.

A table comparing the key features of the subject and predicate devices is provided below.

Element	Proposed Device: Pall® QPoint™ Water Filter (K163609)	Predicate Device: Pall-Aquasafe™ Water Filter (K153434)
Indications for Use	The QPoint™ Water Filter Capsule is intended to be used to filter EPA (Environmental Protection Agency in USA) quality drinking water. By retaining bacteria, fungi and protozoa, 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 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.
Filter Media	0.2 micron sterilizing-grade membrane Highly asymmetric pre-filter membrane, two layers (~30 microns to ~1 micron, and ~1 micron to 0.2 micron)	0.2 micron sterilizing-grade membrane Integrated asymmetric pre-filter membrane, one layer (~1 micron to 0.2 micron)
Effective Filtration Area	Approximately 620 cm^2 (nominal)	Approximately 550 cm^2 (nominal)
Filter Life	62 days	31 days
Filter Assembly	Disposable filter capsule designed for use with a reusable docking station.	Disposable filter capsule
Plumbing Supply Connection	Reusable Docking Station	Quick connector adapter
Maximum operating temperature	Maximum influent temperature 75 °C (167 °F) for a total cumulative period of 90 minutes over the life of the Filter Capsule.	Maximum influent temperature 70 °C (158 °F) for a total cumulative period of 30 minutes over the life of the filter.
Shelf Life	5 year accelerated aging; Real time testing ongoing	3 years
Materials of Construction		
Filter Capsule/ Housing/ Endcap	Polyester containing pigment with bacteriostatic additive moulded into it.	Polyester containing pigment with bacteriostatic additive moulded into it.

Element	Proposed Device: Pall® QPoint™ Water Filter (K163609)	Predicate Device: Pall-Aquasafe™ Water Filter (K153434)
Filter Media	Double layer 0.2 micron Supor® membrane with integral pre-filter membrane: Polyethersulphone (PES)	Double layer 0.2 micron Supor® membrane Polyethersulphone (PES)
Membrane Support	Polyester	Polyester
Filter cage	Polypropylene containing pigment with bacteriostatic additive moulded into it	Polypropylene containing pigment with bacteriostatic additive moulded into it
Operation		
Feed Water Source	In-premise drinking water system plumbing	In-premise drinking water system plumbing
Bacteria Removal	> 10^7 CFU *B. diminuta*/cm^2 effective filtration area	> 10^7 CFU *B. diminuta*/cm^2 effective filtration area

Performance Data:

The following non-clinical tests were performed to demonstrate the safety and effectiveness of the Pall® QPoint™ Water Filter Capsules (0.2 micron sterilizing grade filters) and support expansion of the waterborne microorganisms referenced in the indications for use to include fungi and protozoa in addition to bacteria.

- *Sterilization Validation*: The QPoint™ Water Filter Capsules are sterilized by gamma radiation validated and controlled in accordance with ISO 11137-1, ISO11137-2 and 11137-3 to ensure a minimum Sterility Assurance Level (SAL) of 10^{-6}.
- *Shelf Life/Stability:* Shelf life testing on final, finished, sterile devices after accelerated aging.
- *Packaging Integrity:* Transit trials performed on the filter capsules and their packaging met all requirements. Unit packages are both visually inspected and mechanically tested for seal integrity prior to release.
- *Membrane Integrity:* The filter capsules are 100% in-process tested for forward flow and leaks, confirmed with bacterial challenge testing.
- *Microbial Retention Verification:* Testing per ASTM F838-05 using *Brevundimonas diminuta* at a challenge level of ≥ 1 x 10^7 colony forming units (CFU) per cm^2 of effective filtration area. All analysis membranes were found to be free of the test organism. There was also no detection of the challenge organism in filtered water samples tested for retention of *Legionella pneumophila, Pseudomonas aeruginosa, Escherichia coli* and *Mycobacterium gordonae* (>1 x 10^7 CFU/cm^2 effective filtration area challenge).
- *Microbial Retention in Intermittent Use:* Testing per ASTM F838-05 confirmed that the Pall QPoint™ Water Filter Capsules retain the microbial challenge organisms *Brevundimonas diminuta*, *L. pneumophila*, and *Aspergillus fumigatus* during typical intermittent use for a period of 62 days. All analysis membranes were found to be free of the test organism.

- *Maximum Operating Temperature and Pressure Rating:* Tested device operation at a continuous influent temperature of 60°C (140°F) and a maximum influent temperature of 75°C (167°F) for a total cumulative period of 90 minutes over the life of each filter capsule. The filter capsules were also tested to withstand a maximum operating pressure of 5 bar (~75 psi) at continuous 60°C (140°F) influent temperature over the life of the filter. Testing demonstrated that the filters maintain their integrity over their simulated service life.
- *Flow Rate Testing:* At water pressures reflecting normal use conditions, flow rates through the Filter Capsules ranged from 5.7 L/min at ~15 psi to 18.8 L/min at ~75 psi.
- *Additive Evaluation:* The bacteriostatic additive incorporated within the housing polymer was shown to successfully reduce external microbial contamination by >99.5% after 24 hours contact.
- *Biocompatibility:* All tests were passing, demonstrating conformance to ISO 10993-1.
    - Cytotoxicity (L929 MEM elution) per ISO 10993-5:2009
    - Sensitization and intracutaneous injection per ISO 10993-10:2010
    - Systemic injection and material-mediated rabbit pyrogen per ISO 10993-11:2006

The packaging integrity and bacterial challenge testing were conducted after accelerated aging, to confirm that the performance of the product does not degrade over time. All filter capsules tested retained integrity and maintained a safety margin above maximum operating pressure after the equivalent (in accelerated aging) of 5 years in storage.

Conclusion:

The Pall® QPoint™ Water Filter Capsule is as safe and effective as the Pall-Aquasafe™ Water Filter (K153434). The subject device has the same intended use and very similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended therapeutic use of the device, nor do they affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the devices raise no new questions of safety or effectiveness. Performance data further support the subject device's safety and performance as compared to the predicate. Thus, the QPoint™ Water Filter Capsule is substantially equivalent.