June 29, 2018

Ecolab Inc.
Jennifer Willner, RAC
Sr. Director Regulatory Affairs
One Ecolab Place
St. Paul, MN 55102

Re: K173164
Trade/Device Name: Ecolab POU Water Filter
Regulation Number: 21 CFR 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: Class II
Product Code: NHV
Dated: May 29, 2018
Received: May 30, 2018

Dear Jennifer Willner:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173164

Device Name
Ecolab POU Water Filter

Indications for Use *(Describe)*

The ECOLAB POU Water Filters are intended to operate on EPA quality drinking water sources as a microbial retention filter. ECOLAB POU Water Filters are suitable for the control of bacteria equal to or greater in size than Brevundimons diminuta. The POU Filters are suitable for general point of use infection control for procedures such as superficial wound cleansing, cleaning of equipment, washing of surgeon's hands and bathing where the reduction of such microorganisms in the water is desired.

The POU Filters are not intended for use in the production of USP sterile water for use in infusion, injection or production of fluids for use in dialysis treatments.

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.

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510(k) Summary

Manufacturer:	Ecolab Inc. One Ecolab Place St Paul, MN 55102 USA Establishment Registration Number: 9009921
Contact:	Jennifer Willner, RAC Sr. Director Regulatory Affairs Ecolab Inc. One Ecolab Place, St Paul, MN 55102 USA Phone: 651 250 4348
Date Prepared	May 24, 2018
Trade Name	Ecolab POU Water Filter
Classification	Class II
Regulation Name	Water purification system for hemodialysis
Regulation Number	21 CFR 876.5665
Product Code	NHV
Predicate Device	Evoqua Water Technologies, Nosogard Filters, K153784
Device Description	The Ecolab POU Water Filter is a disposable Polyethersulfone (PES) membrane filter sealed in a white polypropylene housing designed to be installed by facility personnel at point of use locations where the control of bacteria in EPA quality drinking water is desired for hand-washing, bathing, showering and instrument cleaning applications. These filters are designed to be installed as attachments to faucets or as a handheld shower head attached to a water outlet.
Indication for Use	The ECOLAB POU Water Filters are intended to operate on EPA quality drinking water sources as a microbial retention filter. ECOLAB POU Water Filters are suitable for the control of bacteria equal to or greater in size than Brevundimons diminuta. The POU Filters are suitable for general point of use infection control for procedures such as superficial wound cleansing, cleaning of equipment, washing of surgeon's hands and bathing where the reduction of such microorganisms in the water is desired. The POU Filters are not intended for use in the production of USP sterile water for use in infusion, injection or production of fluids for use in dialysis treatments.

Substantial Equivalence Comparison Table		
	Subject Device	Predicate Device
510(k) Number	K173164	K153784
Trade Name	Ecolab POU Water Filter	Nosogard Filters
Manufacturer	Ecolab Inc.	Evoqua Water Technologies, LLC.
Indications for Use	The ECOLAB POU Water Filters are intended to operate on EPA quality drinking water sources as a microbial retention filter. ECOLAB POU Water Filters are suitable for the control of bacteria equal to or greater in size than Brevundimons diminuta. The POU Filters are suitable for general point of use infection control for procedures such as superficial wound cleansing, cleaning of equipment, washing of surgeon's hands and bathing where the reduction of such microorganisms in the water is desired. The POU Filters are not intended for use in the production of USP sterile water for use in infusion, injection or production of fluids for use in dialysis treatments	The NOSOGARD line of filters are intended to operate on EPA quality drinking water sources as a microbial retention filter. NOSOGARD filters are available in models suitable for the control of bacteria equal to or greater in size than Brevundimons diminuta and models for microbial removal equal to or greater than Legionella pneumophila. The NOSOGARD is suitable for general point of use infection control for procedures such as cleaning, rinsing of equipment, hand washing and bathing where the reduction of such microorganisms in the water is desired. The Nosogard is not intended for use in the production of USP sterile water for use in infusion, injection or production of fluids for use in dialysis treatments.
Device Description	A disposable Polyethersulfone (PES) membrane filter sealed in a white polypropylene housing designed to be installed by facility personnel at point of use locations where the control of bacteria in EPA quality drinking water is desired for hand-washing, bathing, showering and instrument cleaning applications. These filters are designed to be installed as attachments to faucets or as a handheld shower head attached to a water outlet.	A disposable Polyethersulfone (PES) membrane filters sealed in a polypropylene housing designed to be installed by facility personnel at point of use locations where the control of bacteria in the drinking water supply is desired for device cleaning, handwashing and bathing applications. These filters are designed to be installed as attachments to faucets or as a handheld shower head.
Feed Water Source	SAME	Drinking water plumbing at point of use.
Feed Water Quality	SAME	PotableWater as defined by the EPA National Primary DrinkingWater Regulations (EPA Quality Water)

Substantial Equivalence Comparison Table		
	Subject Device	Predicate Device
Useful Life	Up to 7 days and 31 days depending on model	Up to 7 days or 31 days or 62 days depending on model
Maximum Inlet Pressure	89.9 psi (6.2 bar): tap filters 79.8 psi (5.5 bar): shower wands	89.9 psi (pounds / square Inch) for all models
Sterile Device	SAME	Shipped in sterile condition and package
Casing	SAME	Polypropylene
Filter Element(s)	SAME	Polyethersulfone (PES) pleated membrane
Bacteria Reduction*	SAME	$> 10^7$

Device Description & Summary of Technological Characteristics:

The ECOLAB POU Water Filter is a disposable polyethersulfone (PES) membrane filter sealed in a white polypropylene housing designed to be installed by facility personnel at point of use locations where the control of bacteria in EPA quality drinking water is desired for hand- washing, bathing, showering and instrument cleaning applications. These filters are designed to be installed as attachments to faucets or as a handheld shower head attached to a water outlet. The POU water filters are supplied sterile for single use and are not intended to be resterilized.

Ecolab POU Filters Models and Maximum Service Life Once Installed

Model (REF)	**Description**	**Max. Use Days**	**Type**	**Inlet**	**Outlet**
6065845	7-Day Sterile Tap Filter w/Spray Outlet	7	Tap	Quick connect	Spray
6065846	7-Day Sterile Tap Filter w/Nozzle Outlet	7	Tap	Quick connect	Nozzle
6065702	31-Day Sterile Tap Filter w/Spray Outlet	31	Tap	Quick connect	Spray
6065703	31-Day Sterile Tap Filter w/Nozzle Outlet	31	Tap	Quick connect	Nozzle
6065704	31-Day Sterile Shower Wand Filter	31	Shower wand	½" NPT	Shower

The ECOLAB POU Water Filters have the same intended use as the predicate device. The ECOLAB POU Water Filters and the predicate device are constructed of the same materials; both incorporate a 1µm polypropylene prefilter and a 0.2µm polyethersulfone pleated filter membrane. Both products are available in tap filter and shower wand configurations and have the same range of maximum service life from 7 days to 30 days. Both devices are supplied sterile in packaging capable of maintaining a sterile barrier for the labeled shelf life of three years.

The predicate devices have models suitable for the control of bacteria equal to or greater in size than *Legionella peumophila* and models suitable for retention of the smaller *Brevundimons diminuta* bacteria. All ECOLAB POU Water Filters are suitable for retention of the smaller *Brevundimons diminuta* over the maximum service life of the model.

Non-Clinical Performance Testing

All ECOLAB POU Water Filters retained the test organism *Brevundimonas diminuta* challenge of ≥ 10^7 organisms/cm² and prevented bacterial grow-through over the service life of each model when tested according to ASTM F838-15 Standard Test Method for Determining Bacterial Retention of Membrane Filters.

Filter flow rates at 3 bar inlet pressure are 7-Day tap filter – 6.3 L/min; 14-Day tap filter – 6.5 L/min; 31-Day tap filters – 6 L/min.

Simulated Use Cyclic Pulse Testing demonstrates that the tap filters maintain microbial retention effectiveness, as measured by diffusional flow integrity test, after continuous use repeated shocks of 89.9 psi (6.2 bar) at 151°F (66°C). The shower wand filters maintain microbial retention effectiveness, as measured by diffusional flow integrity test, after continuous use repeated shocks of 79.8 psi (5.5 bar) at 122°F (50°C).

The Ecolab POU Water Filters are provided sterile in sterile packaging. Testing according to ISO 11137-1 and ISO 11137-2, *sterilization of health care products*, verifies that the gamma irradiation process assures product sterility.

Package testing according to ISO 11607-1 and 11607-2, *Packaging For Terminally Sterilized Medical Devices*, has demonstrated that the packaging is capable of maintaining a sterile barrier for the labeled 36 month shelf life. Testing also verified that the filters retain their functional characteristics through 36 months.

Biocompatibility Testing Results

Biocompatibility of the Ecolab POU Water Filters was verified according the biocompatibility tests performed on devices after exposure to all manufacturing conditions and gamma sterilization. All biocompatibility testing was conducted in accordance to ISO 10993-5 and under GLP 21 CFR Part 58 Regulations:

Biological Effect	**Applicable EN ISO 10993 Standard**
Cytotoxicity	Part 5: Tests for Cytotoxicity – In Vitro Methods
Irritation	Part 10: Tests for Sensitization and Irritation
Sensitization	Part 10: Tests for Sensitization and Irritation
Acute Systemic Toxicity	Part 11: Tests for Systemic Toxicity
Material Mediated Pyrogenicity	Part 11: Tests for Systemic Toxicity