DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 21, 2016

Evoqua Water Technologies, LLC
Robert Dudek
Regulatory Manager
10 Technology Drive
Lowell, Massachusetts 01851

Re: K153784
Trade/Device Name: Nosogard Filters
Regulation Number: 21 CFR 876.5665
Regulation Name: Water Purification System For Hemodialysis
Regulatory Class: Class II
Product Code: NHV
Dated: September 11, 2016
Received: September 20, 2016

Dear Robert Dudek:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental 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)*
K153784

Device Name
NOSOGARD FILTERS

Indications for Use *(Describe)*
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.

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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510k Summary (K153784) of the Nosogard™ Filters

Submitter:	Evoqua Water Technologies, LLC. 10 Technology Drive Lowell, MA 01851 Establishment Registration - Pending
Contact:	Robert Dudek Evoqua Water Technologies, LLC. 10 Technology Drive Lowell, MA 01851 E-Mail: Robert.Dudek@Evoqua.com Phone: 978-614-7359 Fax: 978-441-6037
Date Prepared	September 11, 2016 (amended 10-20-2016)
Trade Name	Nosogard Filters
Proposed Class	Class II
Classification Name and Number	21 CFR Part 876.5665 Water Purification Device, General Medical Use
Product Code	NHV
Predicate Device 1	Nephros Inc. – DSU-H™ and SSU-H™ Filters – K141731
Predicate Device 2	PrisMedical – MainStream™ Water Purification Device – K012716
Device Description	Nosogard Filters are 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.
Intended Use	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 peumophila. 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 bacterial 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.

	Evoqua Nosogard Filters	Predicate Device 1	Predicate Device 2
510(k) Number	K153784	K141731	K012716
Manufacturer Name	Evoqua Water Technologies, LLC.	Nephros Inc.	PrisMedical
Indications for Use	The Nosogard Filters are intended to operate on EPA quality drinking water sources as a microbial retention filter and are suitable for general point of use infection control for procedures such as cleaning, rinsing of equipment, hand washing and bathing where the reduction of bacterial 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.	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: - 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
Feed Water Source	Drinking water plumbing at point of use.	In-Line plumbing	Feed Container (tank)

	Evoqua Nosogard Filters K153784	Predicate Device 1	Predicate Device 2
Feed Water Quality	Potable Water as defined by the EPA National Primary Drinking Water Regulations (EPA Quality Water)	EPA Quality Water	EPA Grade Water
Useful Life	Up to 7 days, 31 days or 62 days depending on model	up to 3 Mo. (SSU-H) up to 6 Mo. (DSU-H)	3 Liters
Maximum Inlet Pressure	89.9 psi (pounds / square inch	75 psi (SSU-H) 100 psi (DSU-H)	Gravity feed (< 10 psi)
Sterile Device	Shipped in sterile condition and package	No	No
Casing	Polypropylene	ABS Plastic	Polycarbonate Plastic
Bacteria Filter Element(s)	Polyethersulfone (PES) pleated membrane	Polysulfone Ultrafiltration Hollow Fiber	Polyethersulfone flat membrane
Performance Claims	Evoqua Nosogard Filters	Predicate Device 1	Predicate Device 2
Bacteria Reduction	Greater than 10^7	Greater than 10^{11}	Greater than 10^7
Virus Reduction	No performance claims	Greater than 10^8	Greater than 10^4
Endotoxin Reduction	No performance claims	Greater than 10^5	Greater than 10^4
Organic Reduction	No performance claims	N/A	TOC reduced to less than 1 ppm
Ion Reduction	None	N/A	Greater than 10^3 dissociable ions

Table 1 - Comparison to predicate devices

Device Description & Summary of Technological Characteristics:

The Nosogard Filter are 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 EPA quality 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 attached to a water outlet. Further details of the technology may be located in the 510k submission Section 12, Materials and Design. The filter is not intended or marketed as a device to reduce endotoxin or virus in general washing applications and the difference to predicate devices is not applicable. Biocompatibility testing (located in the 510k submission Section 16, Biocompatibility) demonstrates that all materials are safe for use in this

application and are free of harmful extractable or leachable chemicals. These materials of construction are commonly used in other medical devices that have been previously approved for use in products regulated under 21CFR876.5665

The product models are based on the anticipated useful life of the product in specific roles. These are identified as filters suitable for maximum use periods of 7 days (type Nosogard 7/31 Filter), 31 days (Nosogard 31 Day Filter) or 62 days (Nosogard 62 Day Filter) depending on the size of the bacterial component targeted for removal and other particulate matter in the source water. Internal differences in membrane arrangement, density of pleating and pre-filtration elements within the cartridge determine the maximum anticipated useful life of the filter. The Nosogard line of filters are offered with a choice of style of connection to water source, outlet flow type and both a large and normal size 7/31 model. In addition handheld shower wands are available in 31 and 62 day models. Each model is identified by a unique part number and information regarding application is also identified on the product labeling.

NOSOGARD® FILTER MODELS

Part Number	Description	Inlet Connection	Outlet Flow	Microbial Performance	
				Brevundimons diminuta (or larger)	Legionella pneumophila (or larger)
W2T42138	Nosogard 7/31 Filter (1.25" size)	Quick Connect	Stream	Not to exceed 7 days	Not to exceed 31 days
W2T42134	Nosogard 7/31 Filter (1.25" size)	Quick Connect	Shower	Not to exceed 7 days	Not to exceed 31 days
W2T42138	Nosogard 7/31 Filter (2.5" size)	Quick Connect	Stream	Not to exceed 7 days	Not to exceed 31 days
W2T42138	Nosogard 7/31 Filter (2.5" size)	Quick Connect	Shower	Not to exceed 7 days	Not to exceed 31 days
W2T42138	Nosogard 7/31 Filter (2.5" size)	Quick Connect	1/2" NPT	Not to exceed 7 days	Not to exceed 31 days
W2T82022	Nosogard 31 Day Filter (1.25" size)	Quick Connect	Shower	Not to exceed 31 days	Not to exceed 31 days
W2T82022	Nosogard 31 Day Filter (1.25" size)	Quick Connect	Stream	Not to exceed 31 days	Not to exceed 31 days
W2T82022	Nosogard 62 Day Filter (1.25" size)	Quick Connect	Shower	Not to exceed 62 days	Not to exceed 62 days
W2T82022	Nosogard 62 Day Filter (1.25" size)	Quick Connect	Stream	Not to exceed 62 days	Not to exceed 62 days
W2T82022	Nosogard 31 Day Shower Wand	1/2" NPT	Shower	Not applicable	Not to exceed 31 days
W2T82023	Nosogard 31 Day Shower Wand	1/2" NPT	Shower	Not to exceed 31 days	Not to exceed 31 days
W2T82023	Nosogard 62 Day Shower Wand	1/2" NPT	Shower	Not to exceed 62 days	Not to exceed 62 days

Table 2 – Nosogard Models & Part Numbers

Non-Clinical Performance Testing

Results reflected in summary Table 3, Nosogard Performance Testing are contained in the submission sections titled Biocompatibility and Bench Testing in full detail.

All filter designs were placed in test assemblies and operated continuously for a period at least equal to the useful life of the model with repetitive inoculations of the subject microbe. Testing for bacterial reduction rates of 10 to the 7th were demonstrated successful at the time of installation and remained effective throughout the use period stated for each model using the ASTM F838 *Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration.* This reduction rate testing and ASTM F838 standard was also utilized to demonstrate bacterial grow through of the membrane did not occur during the stated use period for each model.

All filter designs and housings were tested to pressures equal to or greater than stated operating limits to demonstrate the Nosogard filter retains integrity at the stated operating limits. Integrity testing and pressure testing was conducted using the protocols in ASTM F838 *Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration*.

Drop testing was conducted to demonstrate that the filter was not compromised at the stated maximum operating pressure and maximum operating temperatures after being subjected to a 6 foot unprotected drop. Integrity was verified with membrane diffusional flow testing.

Simulated use testing (cycle testing) demonstrates the Nosogard filter successfully retains integrity after exposure to repeated pressurization, flow and depressurization cycles at maximum stated temperatures and pressure. Integrity was verified with diffusional flow testing.

Sterilization testing conducted in accordance with ANSI/AAMI/ISO 11137-2:2012 *Sterilization of health care products* was conducted post gamma irradiation and demonstrates that the dosage and exposure utilized is adequate to assure a sterile product prior to release.

Testing of the packaging utilizing ISO 11607:2009 *Packaging for terminally sterilized medical devices* demonstrated the packaging is capable of maintaining a sterile barrier for a period of three years.

Nosogard Performance Testing							
Nosogard Model	**Parameter**	**Minimum Objective of Non-Clinical Testing & Materials for Nosogard Brand Filters**	**Passing Result?**	**Nosogard Model**	**Parameter**	**Minimum Objective of Non-Clinical Testing & Materials for Nosogard Brand Filters**	**Passing Result?**
Nosogard 7/31 Filter	7day, B.dim grow through.	No grow through ≤7days when challenge with >10^7 cfu/cm² *Brevvundimonas diminuta*	Passed	NOSOGARD 31 Day shower wand (handheld shower)	31day, legionella grow through.	No grow through ≤31days when challenge with >10^7 cfu/cm² *Legionella pneumophila*	Passed
	31day, legionella grow through.	No grow through ≤31days when challenge with >10^7 cfu/cm² *Legionella pneumophila*	Passed		Flow Rate	0.79ft³/min at 44psi inlet pressure	Passed
	Flow rate	1.25" = 0.22ft³/min at 44psi inlet pressure 2.5" = 0.40ft³/min at 29psi inlet pressure	Passed		Housing burst pressure	10Barg at 40°C	Passed
	Housing burst pressure	10Barg at 40°C	Passed		Pulse testing	Integral post 124 cycles x 7mins x 0-5Barg pulses at 40°C	Passed
	Pulse testing	7day: Integral post 2000 cycles x 5mins x 0-6.2Barg pulses at 66°C 31day: Integral post 2000 cycles x 5mins x 0-6.2Barg pulses at 66°C	Passed		Shelf life	Packaging forms a sterile barrier for at least 3 years.	Passed
	Shelf life	Packaging forms a sterile barrier for at least 3 years.	Passed		Biocompatibility	Meets requirements in FDA memorandum #G95-1	Passed
	Biocompatibility	Meets requirements in FDA memorandum #G95-1	Passed	NOSOGARD 31 Day shower wand (handheld shower)	31day, B.dim grow through.	No grow through ≤31days when challenge with >10^7 cfu/cm² *Brevvundimonas diminuta*	Passed
NOSOGARD 31 Day Filter	31day, B.dim grow through.	No grow through ≤31days when challenge with >10^7 cfu/cm² *Brevvundimonas diminuta*	Passed		Flow Rate	0.32ft³/min at 44psi inlet pressure	Passed
	Flow Rate	0.19ft³/min at 44psi inlet pressure	Passed		Housing burst pressure	10Barg at 40°C	Passed
	Housing burst pressure	10Barg at 40°C	Passed		Pulse testing	Integral post 124 cycles x 7mins x 0-5Barg pulses at 40°C	Passed
	Pulse testing	Integral post 2000 cycles x 5mins x 0-6.2Barg pulses at 66°C	Passed		Shelf life	Packaging forms a sterile barrier for at least 3 years.	Passed
	Shelf life	Packaging forms a sterile barrier for at least 3 years.	Passed		Biocompatibility	Meets requirements in FDA memorandum #G95-1	Passed
	Biocompatibility	Meets requirements in FDA memorandum #G95-1	Passed	NOSOGARD 62 Day shower wand (handheld shower)	62day, B.dim grow through.	No grow through ≤62days when challenge with >10^7 cfu/cm² *Brevvundimonas diminuta*	Passed
NOSOGARD 62 Day Filter	62day, B.dim grow through.	No grow through ≤62days when challenge with >10^7 cfu/cm² *Brevvundimonas diminuta*	Passed		Flow Rate	0.39ft³/min at 44psi inlet pressure	Passed
	Flow Rate	0.25ft³/min at 44psi inlet pressure	Passed		Housing burst pressure	10Barg at 40°C	Passed
	Housing burst pressure	10Barg at 40°C	Passed		Pulse testing	Integral post 248 cycles x 7mins x 0-5Barg pulses at 40°C	Passed
	Pulse testing	Integral post 4000 cycles x 5mins x 0-6.2Barg pulses at 66°C	Passed		Shelf life	Packaging forms a sterile barrier for at least 3 years.	Passed
	Shelf life	Packaging forms a sterile barrier for at least 3 years.	Passed		Biocompatibility	Meets requirements in FDA memorandum #G95-1	Passed
	Biocompatibility	Meets requirements in FDA memorandum #G95-1	Passed				

Table 3 – Non Clinical Performance Test Results

Biocompatibility Testing Results

Biocompatibility of Nosogard Filters was tested in the form of fully assembled products and passed the following tests for biocompatibility:

1. General Chapter <88> of the United States Pharmacopeia and National Formulary, Section USP Class VI Plastics
    a. Intracutaneous Reactivity Testing
    b. Acute Systemic Injection Testing

    c. Intramuscular Implant Testing
2. General Chapter <87> of the United States Pharmacopeia, Biological Reactivity Tests, In Vitro
    a. Minimal Essential Media Elution Test for Cytotoxicity
3. ISO 10993:2010 Biological evaluation of medical devices Part 5:
    a. Part 5: Tests for in vitro cytotoxicity
    b. Part 10: Tests for irritation and Skin Sensitization

Summary of Standards Utilized in the Design and Performance Evaluation of the Nosogard

- General Chapter <88> of the United States Pharmacopeia and National Formulary, Section USP Class VI Plastics
- General Chapter <87> of the United States Pharmacopeia, Biological Reactivity Tests, In Vitro
- ISO 10993:2010 Biological evaluation of medical devices
- ASTM F838 Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration
- ANSI/AAMI/ISO 11137-2:2012 Sterilization of health care products
- ISO 11607:2009 Packaging for terminally sterilized medical devices
- Blue Book Memorandum #G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

Summary of Substantial Equivalence:

Based on non-clinical performance testing, the Nosogard filters have been found to be substantially equivalent to the predicate PrisMedical MainStream Filter (K012716) and Nephros DSU & SSU filters (K141731) for the intended use.