October 25, 2019

aqua-tools
Virginie Grondin
Medical Devices Quality and
Regulatory Affairs Manager
26 Rue Charles Edouard Jeanneret
78300 POISSY
FRANCE

Re: K191563
Trade/Device Name: FILT'*RAY* 2G Disposable Water Filters
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: NHV
Dated: September 17, 2019
Received: September 23, 2019

Dear Virginie Grondin:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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
Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K191563

Device Name
FILT'RAY2G Diposable Water Filter

Indications for Use *(Describe)*
The aqua-tools FILT'RAY 2G Disposable 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

aqua-tools
INFECTION CONTROL
SOLUTIONS

510(K) SUMMARY

I. SUBMITTER

Company Name: aqua-tools

Contact Person : Ms. Virginie S. Grondin
virginie.grondin@aqua-tools.com

Date Prepared: May 28th, 2019

II. DEVICE

Trade Name: FILT'*RAY* 2G Disposable Water Filters
Common Name: System, Water purification, General medical use
Device Classification: 21 CFR 876.5665, Product code NHV
Classification Name: Water purification system for hemodialysis
Device Class: Class II
Panel: Gastroenterology/Urology

III. PREDICATE DEVICES

Primary Predicate Device: Pall-Aquasafe™ Water Filters (K153434)
21 CFR 876.5665, Class II, NHV

Additional Predicate Devices: Evoqua Nosogard Filters (K153784)
Nephros, Inc. S100 Point of Use Filters (K153084)

IV. DEVICE DESCRIPTION

The FILT'*RAY* 2G Disposable Water Filters are intended to produce bacteriologically controlled, purified water for general medical uses (e.g., washing of surgeon's hands, surgical instruments, and cleansing). These devices retain bacteria including opportunistic waterborne pathogenic microorganisms via a hollow fiber microfiltration technology with a corresponding pore size of 0.1 µm nominal / 0.2 µm absolute.

This microfiltration technology ensures that the purified water will meets the criteria of bacteriologically controlled water that presents a higher bacteriological quality than the water of the distribution network by retaining bacteria, including Legionella spp., L. pneumophila, Pseudomonas aeruginosa and other opportunistic waterborne pathogenic microorganisms. Of note, the subject FILT'*RAY* ^{2G} devices do not contain latex, nor tissues or by-product animal origins, nor derived of blood or any substance considered as a medicine. The subject FILT'*RAY* ^{2G} devices are provided sterile and are designed to be used for 1 month up to 4 months after initial connection and depending on the specific model.

V. INDICATIONS FOR USE

The aqua-tools FILT'*RAY* ^{2G} Disposable 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and predicate devices have identical or similar indications for use and yield water that is suitable for drinking and washing. The subject FILT'*RAY* ^{2G} Disposable Water Filter device is also similar in its system configuration (e.g., shower, faucet, in-line filters), use specifications (use life, pressure rating, water source/network), and in other significant design and technological features. The subject and predicate devices utilize the same fundamental technology that consists of a sterilizing grade filter[1] membrane that has been validated to retain and remove microorganisms in the water supply. The characteristics of the subject device and the predicate device were assessed and compared via performance testing, as described below. Any minor differences between the subject and predicate devices do not raise new questions of safety or effectiveness. Rather, these differences can and were evaluated through performance testing to determine substantial equivalence.

VII. PERFORMANCE DATA

Non-clinical performance testing was conducted to characterize the subject FILT'*RAY* ^{2G} Disposable Water Filters and is summarized as follows:

Microbial Retention

The ability of the subject FILT'*RAY* 2G Disposable Water Filter to retain a bacterial load greater than 10^7 colony-forming units (CFU)/cm^2 was captured via performance bench testing per ASTM F838-15a: *Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration*. This standard testing was used on water filters that have underwent worst case use. The *Brevundimonas diminuta* test microorganism was not found in any of the filtrates for all tested filters.

Evaluation of Bacteriostatic Agent Effectiveness

The addition of a silver ion-based bacteriostatic agent into the material used to manufacture the housing components was evaluated per ISO 22196: *Measurement of antibacterial activity on plastics and other non-porous surfaces*. These tests were performed on new filters and on aged filters. Per the results of these tests, this agent allows to reduce the external surface contamination by more than 99.9% for *Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus and Methicillin Resistant Staphylococcus aureus* (MRSA). Ageing of the samples had no impact on the efficacy of the treated samples.

Silver Ion Testing

The presence of any silver-based ions in the water filtered through the FILT'*RAY* 2G Disposable Water Filters was quantified via inductively coupled plasma mass spectrometry (ICP/MS) and found to be less than the quantification limit (i.e., <1.0µg/L) and are in compliance with the World Health Organization (WHO) guidelines without risk to health.

Maximum Operating Temperature and Pressure Rating

Testing was conducted at up to 5 bar as well as up to 70ºC (for a continuous period of 30 minutes) to ensure that the subject filters were able to not only withstand these conditions, but also adequately retain bacteria at a greater than 7 log reductions after filtration of water at these conditions.

Flow Rate Testing

All filter models were subjected to a flow rate/pressure test with water pressures varying from 1 to 5 bar (on the filter input) and were found to have adequate flow for use at these various inputs.

[1] Sterilizing grade filter is defined in "American standard Test Method ASTM F838-15a and in FDA - Guidance for Industry - Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice" as a filter ability to sustain a bacterial challenge of 10^7 CFU of *Brevundimonas diminuta* per cm2 of filtration surface.

Biocompatibility

The subject FILT'*RAY* 2G Disposable Water Filter device is proposed to be used for washing, drinking, superficial wound cleansing, cleaning of equipment used in medical procedures and washing of surgeon's hands. Therefore, given the intended use, nature and degree of tissue contact and exposure duration during clinical use, the subject device is considered a surface device, contacting breached or compromised surfaces repeatedly for limited duration of contact (< 24 hours). The 24 hour-exposure duration is considered as worst-case cumulative patient-contacting hours, even though there is potential for repeat use of the same or a new device during its intended use. Therefore, per the FDA Guidance on the "Use of International Standard ISO 10993-1," the following tests for biocompatibility evaluation of the subject FILT'*RAY* 2G Disposable Water Filter device have been performed: cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, and material mediated pyrogenicity testing. The NAMSA tests reports indicate that it is safe for use in medical devices, as evidenced by the passing results of cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity, and material mediated pyrogenicity testing, which are required for this classification.

Sterilization Testing

The FILT'*RAY* 2G Disposable Water Filters are available sterile with a use life of 1-month (31 days), 2-month (62 days), 3-month (93 days) and 4-month (124 days). Bioburden was assessed per ISO 11737-1 and 11737-2, and sterilization validation was conducted per ISO 11137-1, parts 1 and 2. The $VD_{Max^{25}}$ method was utilized to characterize a minimum dose of 25kGy to ensure a sterility assurance limit (SAL) of 10^{-6}.

Shelf Life Testing

The packaging and sterilizing grade performance for the subject FILT'*RAY* 2G Disposable Water Filters was conducted via 3-year accelerated aging tests and a 2 years and 9 months real-time aging test. Packaging integrity testing was performed. All results passed the acceptance criteria, and the packaging integrity (and sterility) was determined to be acceptable after sterilization, transportation simulation, and accelerated aging testing. Therefore, the subject FILT'*RAY* 2G Filters remain sterile and produce bacteriologically-controlled water with an expiration date of up to 3 years.

VIII. CONCLUSIONS

Comparison of the indications for use, technical characteristics, as well as performance of the subject and predicate water filters provided in the 510(k) submission, is sufficient to demonstrate substantial equivalence. The information contained in this 510(k) demonstrates that the FILT'*RAY* 2G Disposable Water Filters are as safe and effective as the predicate device. With identical indications for use and similar technological characteristics that were evaluated by performance testing, the aqua-tools FILT'*RAY* 2G Disposable Water Filters are substantially equivalent to the predicate device.