February 13, 2023

AmeriWater, LLC
Brian R. Bowman
Quality & EHS Manager
3345 Stop 8 Road
Dayton, Ohio 45414

Re: K223656
Trade/Device Name: AmeriWater MediQA Reverse Osmosis System (MSP3HF)
Regulation Number: 21 CFR 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: Class II
Product Code: FIP
Dated: January 31, 2023
Received: February 6, 2023

Dear Brian R. Bowman:

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,

Gema Gonzalez -S

Gema Gonzalez
Acting 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223656

Device Name

AmeriWater MediQA Reverse Osmosis System (MSP3HF)

Indications for Use *(Describe)*

The AmeriWater MediQA Reverse Osmosis System is one component of a water treatment system designed to pre-treat and purify potable water using reverse osmosis for making dialysate for hemodialysis applications. The device is intended to be a component in a complete water purification system, and is not a complete water treatment system. It must be preceded by pre-treatment devices, and may need to be followed by post-treatment devices as well to meet current AAMI and Federal (U.S.) standards. The AmeriWater MediQA is intended for use in water rooms in a hospital, clinic, or dialysis center. The device includes an integrated heat sanitization process.

The MediQA is available in both single pass and double pass models that supply from 4.5 to 16.0 gallons per minute (gpm) of product water. Model MSP1 is a single pass, single membrane RO that produces up to 5.0 gpm of product water. Model MSP2 is a single pass, dual-membrane RO that produces up to 9.4 gpm of product water. Model MSP3 is a single pass, 3-membrane RO that produces up to 12.6 gpm of product water. Model MSP3HF is a high-flow, single pass, 3-membrane RO that produces up to 16.0 gpm of product water. Model MDP1 is a double pass, 2-membrane RO that produces up to 5.0 gpm of product water. Model MDP2 is a double pass, 3-membrane RO that produces up to 7.0 gpm of product water. Model MDP3 is a double pass, 4-membrane RO that produces up to 10.0 gpm of product water. Model MDP4 is a double pass, 5-membrane RO that produces up to 12.0 gpm of product 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.

AmeriWater
The Water Purification Specialists

January 31, 2023

510(K) SUMMARY

Submission Type: Special 510(K): Device Modification - New Model

Existing 510(K) Number: K131904

Submitter: AmeriWater, LLC

Contact: Brian R. Bowman, Quality & EHS Manager
3345 Stop 8 Road, Dayton, OH 45414
Phone: (937)461-8833 Fax: (937)461-1988
brian.bowman@ameriwater.com

Proprietary Name: AmeriWater MediQA Reverse Osmosis System, Model MSP3HF

Common Name: Reverse Osmosis System

Classification Name: Water purification system for hemodialysis

Classification: Class II Medical Device under §876.5665
Panel: Gastroenterology
Product Code: FIP

Predicate Device: K131904, AmeriWater MediQA Reverse Osmosis System

Description: This Special 510(K) submission is for the addition of a new model to the AmeriWater MediQA Reverse Osmosis System product line originally cleared for market under 510(k) number K131904. The new model, MSP3HF is complementary to the rest of the product line and is not intended to replace or enhance features of any existing model.

The MSP3HF is a single pass reverse osmosis (RO) that uses pretreated soft water to produce water for hemodialysis applications. The system is capable of producing dialysis quality water at a flow rate up to 16.0 gallons per minute (gpm). The new model, like the predicate device, includes heat sanitization capabilities for the reverse osmosis system.

Model MSP3HF, is identical in design to the existing model MSP3 (K131904) with the exception of the RO pump. While model MSP3 includes a pump with a 20-stage impeller, the new model MSP3HF includes a pump with a 24-stage impeller (currently used on model MDP4). The increase in impeller stages results in the pump forcing more water through the existing membrane elements per unit time. Both the 20-stage pump and the 24-stage pump include the same pump motor. The increase in flow rate does not exceed the operating parameters of the membrane elements per the membrane manufacturer's specifications, and operating pressures remain the same as the predicate device. The increased flow rate does not change the product water quality (level of impurities), and the product water continues to meet all current AAMI/ISO and Federal requirements as confirmed by verification and validation testing. There are no

changes to the software used in the device or to the water contacting materials. All software and materials used in the new model are identical to the predicate device.

The new model does not result in any changes to the heat sanitization process. The temperatures, contact times, and operating pressures remain the same as the predicate device. During the heat sanitization process, the heated water is recirculated through the MediQA system for the duration of the contact time. The flow path, operating pressure, water temperature, and contact time are identical between the predicate device and the new device during heat sanitization. There are no new issues regarding safety or effectiveness of the heat sanitization process.

The scientific concept for the operation of the AmeriWater MEDIQA Reverse Osmosis System is the principle of reverse osmosis. The MEDIQA system uses a pump (RO pump) to apply the pressure required for reverse osmosis. Pretreated soft water enters the MEDIQA through an inlet solenoid valve, filling the feed water tank. The RO pump forces water from the feed tank through the RO membrane elements. The water entering the RO membrane element exits the membrane element in two flow streams. The water forced through the RO membrane element is known as permeate water. It is purified water that meets all current AAMI/ISO and Federal requirements for water used in hemodialysis applications. The water rejected by the membrane contains an increased level of dissolved contaminants. It passes out of the RO module as the second flow stream called concentrate, and is sent to drain.

The built in heat sanitization feature provides heat sanitization of the reverse osmosis membranes and the MEDIQA system's pipe work. Heat sanitization can be activated manually using the HEATSAN buttons on the touch screen display or automatically if timer clock settings are implemented. The frequency of heat sanitization will depend upon usage and application demands. Monitoring of the system for bacterial content is required at regular intervals to determine the optimum frequency for heat sanitization.

Indications for Use: The AmeriWater MediQA Reverse Osmosis System is one component of a water treatment system designed to pre-treat and purify potable water using reverse osmosis for making dialysate for hemodialysis applications. The device is intended to be a component in a complete water purification system, and is not a complete water treatment system. It must be preceded by pre-treatment devices, and may need to be followed by post-treatment devices as well to meet current AAMI and Federal (U.S.) standards. The AmeriWater MediQA is intended for use in water rooms in a hospital, clinic, or dialysis center. The device includes an integrated heat sanitization process.

The MediQA is available in both single pass and double pass models that supply from 4.5 to 16.0 gallons per minute (gpm) of product water. Model MSP1 is a single pass, single membrane RO that produces up to 5.0 gpm of product water. Model MSP2 is a single pass, dual-membrane RO that produces up to 9.4 gpm of product water. Model MSP3 is a single pass, 3-membrane RO that produces up to 12.6 gpm of product water. Model MSP3HF is a high-flow, single pass, 3-membrane RO that produces up to 16.0 gpm of product water. Model MDP1 is a double pass, 2-membrane RO that produces up to 5.0 gpm of product water. Model MDP2 is a double pass, 3-membrane RO that produces up to 7.0 gpm of product water. Model MDP3 is a double pass, 4-membrane RO that produces up to 10.0 gpm of product water. Model MDP4 is a double pass, 5-membrane RO that produces up to 12.0 gpm of product water.

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Statement of Substantial Equivalence: The AmeriWater MEDIQA model MSP3HF is substantially equivalent to the currently marketed AmeriWater MEDIQA model MSP3 cleared for market under 510(k) number K131904. The following table compares and contrasts the predicate device and the new device. This table along with the documentation included in this submission demonstrates that there are no new issues of safety or effectiveness associated with this design change, and that the new device is substantially equivalent to the predicate device.

	Model MSP3 (K131904)	**Model MSP3HF**
Indications for use	The AmeriWater MEDIQA Reverse Osmosis System is a water treatment systems intended for use in hemodialysis applications. The MEDIQA is designed to pre-treat and purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The AmeriWater MEDIQA is intended for use in a hospital, clinic, or dialysis center. The device includes an integrated heat sanitization process.	The AmeriWater MEDIQA Reverse Osmosis System is a water treatment systems intended for use in hemodialysis applications. The MEDIQA is designed to pre-treat and purify potable water for use in making dialysate for hemodialysis and to meet current AAMI and Federal (U.S.) standards. The AmeriWater MEDIQA is intended for use in a hospital, clinic, or dialysis center. The device includes an integrated heat sanitization process.
For Use In:	Hospitals, clinics, or dialysis centers	Hospitals, clinics, or dialysis centers
Power Requirements	230V, 60 Hz, 3-phase	230V; 60 Hz; 3-phase
RO Pump Make/Model	Grundfos / CRNE 5-20	**Grundfos / CRNE 5-24**
RO Membranes	DOW HSRO-390-FF	DOW HSRO-390-FF
Membrane Max Operating Pressure (psi)	600 psi	600 psi
Actual Operating PSI	165 psi	165 psi
Membrane Max Permeate Flow Rate	6.25 gpm/membrane x 3 membranes = 18.75 gpm	6.25 gpm/membrane x 3 membranes = 18.75 gpm
Permeate Flow Rates	12.0 gpm ± 20%	**16.0** gpm ± 20%
RO Contaminant Rejection Rate	>94%	>94%
Product Water Quality	Meets ANSI/AAMI/ISO 23500-1:2019 requirements for dialysis water	Meets ANSI/AAMI/ISO 23500-1:2019 requirements for dialysis water
RO Disinfection	Heat or Chemical	Heat or Chemical
Heat Sanitization For	MEDIQA System only	MEDIQA System only
Heater Power Rating	9.0 kW	9.0 kW
Heated Temperature	185°F	185°F
Heated Water Contact Time (Recirculating)	30 minutes	30 minutes
Working Tank Volume	16 gallons	16 gallons
Heated Water Pressure	60 - 80 psi	60 - 80psi
Water Contacting Materials	316 Stainless Steel, Polyacetal, CPVC, Polyamide Thin-Film Composite, EPDM Polypropylene, Fiberglass (FRP), PTFE, FKM, Viton, Nitrile, PA66, PET Noryl	316 Stainless Steel, Polyacetal, CPVC, Polyamide Thin-Film Composite, EPDM Polypropylene, Fiberglass (FRP), PTFE, FKM, Viton, Nitrile, PA66, PET Noryl

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Summary of Performance Testing: Non-clinical testing was conducted for K131904 to verify and validate the performance of the reverse osmosis function and the efficacy of the heat sanitization in the reduction of bacteria. Results of performance testing indicate that the device produces water that meets current AAMI and Federal (U.S.) standards. Microbiological testing results show evidence that the heat sanitization function is effective in the reduction of bacteria. Verification and validation testing conducted for the new model, MSP3HF, provides evidence that the new model produces water that meets current AAMI and Federal (U.S.) standards and that there is no impact to the function of the heat sanitization process.

Test Conducted	Test Method Description
Essential Performance	Testing to demonstrate conformance with the following standards: • ANSI AAMI ISO 23500-2:2019 Preparation and quality management of fluids for haemodialysis and related therapies - Part 2: Water treatment equipment for haemodialysis applications and related therapies • ANSI AAMI ISO 23500-3:2019 Preparation and quality management of fluids for haemodialysis and related therapies - Part 3: Water for haemodialysis and related therapies
Disinfection Validation	Verification that there is no change to the heat sanitization cycle temperature or contact time for the new model. The effectiveness of the recommended temperature and contact time were validated for the predicate device.
Functional Verification	Complete system testing to verify the performance and functional requirements of the device including pressures, flow rates, temperature, conductivity, rejection rate, operating modes, alarms, and safety features. Additional testing was conducted to demonstrate that the device will continue to produce permeate water that meet AAMI requirements and permeate flow rates remain in a safe operating range when operating with a worst-case feed water temperature.
Biocompatibility	No biocompatibility tests were conducted. Water contacting materials are identical to the predicate device.
Human Factors	No human factors testing was conducted. The new model is identical in intended use, intended users, and intended use environment as the predicate device.
Electrical Safety Testing	Electrical Safety Testing conducted by Intertek as documented in ETL listing report number 100988725LAX-001 (revised 25-Oct-2022) to confirm compliance with: • UL 6010-1:2012 Ed.3+R:19Jul2019 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements. • UL 61010-2-010:2015 Ed.3 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 2-010: Particular Requirements for Laboratory Equipment for the Heating of Materials • CSA C22.2#61010-1-12:2012 Ed.3+U1;U2,A1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements • CSA C22.2#61010-2-010:2015 Ed.4 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 2-010: Particular Requirements for Laboratory Equipment for the Heating of Materials. Note: the device is intended for use in water rooms at a hospital or dialysis clinic, and is not for use in the patient treatment area. The predicate device was also tested to the standards listed above.
EMC Testing	No new EMC testing conducted. The predicate device (K131904) was shown to meet the requirements of EMC standards BS EN 61326:1998/IEC 61326-1:1997, BS EN 61000-3-2:1995, and BS EN 61000-3-2:1995; and the requirements for essential performance and immunity. The design changes implemented to create model MSP3HF (K223656) do not introduce any new EMC-related risks or issues that may affect EMC performance. The electronic components and configuration are identical to the predicate device. The device functions and intended use environments remain unchanged.
Software Validation	No new software validation studies were conducted. There were no changes to the device software. The software is identical to the predicate device.
Animal Studies	No animal studies were conducted.
Clinical Studies	No clinical studies were conducted.

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Conclusion: The information provided in this Special 510(k) demonstrates that the new model, MSP3HF, functions as intended and supports the determination of substantial equivalence to the predicate device. The new model is identical in materials of construction, flow path, and overall design to the predicate device with the exception of a larger pump on the new model. Test results demonstrate that the larger pump does not introduce any new concerns with regard to safety or effectiveness of the device. The Indications for Use, technological characteristics, design, and performance of the MSP3HF are substantially equivalent to those of the predicate device. AmeriWater concludes that the MSP3HF is safe and effective for its intended use.

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