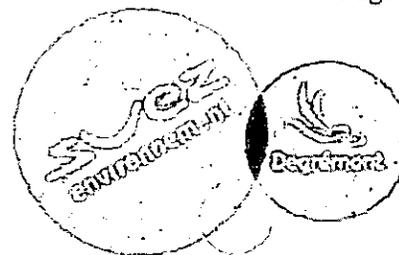


AmeriWater



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510(K) SUMMARY

November 5, 2013

510(K) Number: K131904

Submitter: AmeriWater

Contact: Brian R. Bowman, Quality & Regulatory Administrator
1303 Stanley Avenue, Dayton, OH 45404
Phone: (937)461-8833 Fax: (937)461-1988
brianbowman@ameriwater.com

Proprietary Name: AmeriWater MediQA Reverse Osmosis System

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

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Equivalent Device: K974899, Gambro Central Water Treatment System CWP 100 – WRO H

Device Description: Reverse osmosis, the scientific concept used in the AmeriWater MEDIQA Reverse Osmosis System, is the opposite of osmosis. The MEDIQA system uses a pump to apply the pressure required for reverse osmosis. Potable tap water enters the MEDIQA through an inlet solenoid valve filling the feed water tank. A high pressure pump forces water from the feed tank through the RO modules, each module containing a high performance membrane. The water entering the RO module is split into two flows. The water which passes through the membrane is known as permeate and is purified water. 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 MEDIQA is available as a single pass or a double pass reverse osmosis (RO) unit. In a double pass (two RO stages) system, permeate from the first stage is pressurized by a second high pressure pump and fed to the second stage RO module set. Permeate from the second stage RO module set is fed via a manifold to the distribution loop. Unused permeate returning from the distribution loop is fed back into the feed tank. The concentrate from the first stage is sent to drain while the concentrate from the second stage is returned to the feed water tank for reprocessing. The feed and permeate water flows are monitored at various points in the process to verify temperature, conductivity, and flow. This data is displayed on a touch screen panel to give instant feedback of water quality and process activity. The MEDIQA system is controlled and operated by a touch screen mounted on the machine.

The AmeriWater MEDIQA Reverse Osmosis System also includes a built in heat sanitization feature to enable a heat sanitization of the reverse osmosis membranes and its 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

D - 1

application demands. Monitoring of the system for bacterial content should be conducted 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 12.0 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 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.

Statement of Substantial Equivalence: The AmeriWater MEDIQA is substantially equivalent to the Gambro Central Water Treatment System CWP 100 – WRO H cleared for market under K974899. 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.

	Predicate Device CWP 100 - WRO H (K974899)	AmeriWater MEDIQA
Indications for use	The Gambro Central Water Treatment System CWP 100-WRO H is designed to produce water of adequate quality for hemodialysis, both chemically and microbiologically with an adequate flow, provided that the feed water complies with the existing standards for drinking water and has been properly pre-treated.	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	Hospitals, clinics, or dialysis centers
Power Requirements	120/208V, 60 Hz, 3-phase	208/230V; 60 Hz; 3-phase
Permeate Flow Rates	3.4 – 9.2 gpm	4.5 – 12.0 gpm
RO Disinfection	Chemical	Chemical or Heat
Heat Sanitization For	Water Distribution System	MEDIQA System only
Heater Power Rating	7.0 – 9.0 kW	9.0 kW
Heated Temperature	185°F	185 – 203°F
Working Tank Volume	68 – 87 gallons	16 gallons

Summary of Performance Testing: Non-clinical testing was conducted 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. Clinical studies show evidence that the device, when used in accordance with the instructions for use, will produce water that meets current AAMI and Federal (U.S.) standards for hemodialysis. Test results from biocompatibility testing, software validation, and electrical safety testing indicate that the device is safe and effective for its intended purpose.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 13, 2013

AmeriWater
Brian R. Bowman
Quality & Regulatory Administrator
1303 Stanley Avenue
Dayton, OH 45404

Re: K131904
Trade/Device Name: AmeriWater MediQA Reverse Osmosis System
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: August 12, 2013
Received: August 15, 2013

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. 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/ReportProblem/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 Small Manufacturers, International and Consumer Assistance 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,

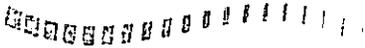
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for

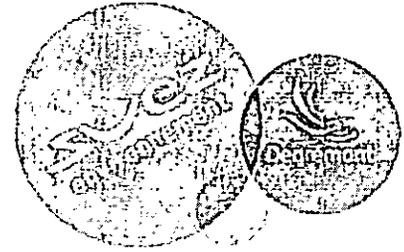
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K131904

Device Name: AmeriWater MediQA Reverse Osmosis System

Indications For Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner-S

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