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AmeriWater®

August 12, 2003

1257 Stanley Avenue Dayton, OH 45404
Phone: 937/461-8833 Phone: 800/535-5585
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www.ameriwater.com

Subject: 510 (K) SUMMARY
510 (K) Number: K021560

AmeriWater Contact: Brian R. Bowman, Quality Manager

Proprietary Name:	AMERIWATER PURIFICATION SYSTEM FOR HEMODIALYSIS
Common Name:	Water Purification System for Hemodialysis
Classification Name:	Water Purification System for Hemodialysis
Classification:	Class II Medical Device under §876.5665

Device Description / Intended Use: The AmeriWater Purification System for Hemodialysis is used to remove organic and inorganic substances and microbial contaminants from water. Purified (or treated) water will then be used to prepare and dilute dialysate concentrate to form dialysate and/or rinse dialyzers for multiple-use dialyzers. AmeriWater does not recommend nor endorse any other use for water treated with AmeriWater systems. AmeriWater further does not endorse any specific hemodialysis or reprocessing procedures or equipment. Please note that Federal Law restricts this device to sale by or on the order of a physician for use as a water treatment device for hemodialysis.

The AmeriWater Purification System for Hemodialysis may include pretreatment components, reverse osmosis and/or deionization, post-treatment components, and a distribution system. All or some of the following components may be included in an AmeriWater Purification System for Hemodialysis based on the customer's needs: Tempering Valve, Float and Pressure Control, Temperature Gauge, Return Flow Diffuser, Backflow Preventor, Booster Pump(s), Multimedia Filter, Water Softener, Carbon Filtration, Micron Prefilter, Chemical Feed System, Reverse Osmosis, Pressure Gauges, Storage Vessel, Deionization, Submicron Filter, Distribution System, Distribution Pump(s), PVC Pipe and Fittings, PVC Ball Valves, PVC Labcock Valves, Automatic Lockout, and System Alarms.

System design is determined by the customer's needs and the water conditions at their facility. Components for the water system are selected based on a survey of the customer's requirements and a complete chemical analysis of the water to be treated. The system is complete with monitors and audible/visible alarms with remote activation in the area of patient care to notify staff of problems if they occur. AmeriWater provides direction and

guidance for monitoring and maintenance of the system to each purchasing facility and 24 hour, 7 days a week, phone support to all owner facilities for the life of the equipment.

AmeriWater has received clearance to market the AmeriWater Purification Systems for Hemodialysis (K991519) containing some or all of the following components: Tempering Valve, Float and Pressure Control, Temperature Gauge, Return Flow Diffuser, Backflow Preventor, Booster Pump(s), Multimedia Filter, Water Softener, Carbon Filtration, Micron Prefilter, Reverse Osmosis, Pressure Gauges, Storage Vessel, Deionization, Submicron Filter, Distribution System, Distribution Pump(s), PVC Pipe and Fittings, PVC Ball Valves, PVC Labcock Valves, Automatic Lockout, and System Alarms.

This 510K submission (K021560) is to obtain clearance to market the AmeriWater Chemical Feed System, and the following RO units (with 510k clearance) in combination with some or all of the components listed above. The brand names of the RO units with 510k clearance that AmeriWater would like to market with the AmeriWater Purification System for Hemodialysis are as follows: The Osmonics 23G Reverse Osmosis Equipment for Water Purification (K931595); the Zyzatech Reverse Osmosis Systems (K964539); the G.E.M. Water Systems Reverse Osmosis System (K944493); the Serv-A-Pure Co. H2Only Reverse Osmosis System (K993520); the Isopure MD Series Reverse Osmosis Systems (K993200); and the U.S. Filter M Series Reverse Osmosis Systems (980182).

The AmeriWater Chemical Feed System is a pretreatment device that is designed to deliver chemicals to the city tap water in order to adjust various chemistries in the water. The chemical feed system is located at the front-end of a water treatment system and may be used for pH adjustment, or to mitigate certain water contaminants to help improve the performance of the complete water system. The chemical feed system is substantially equivalent to the chemical feed in the pretreatment section of the *Water Purification Systems and Components and Portable Reverse Osmosis Systems*, by Zyzatech (K964539) and other chemical feed systems currently legally marketed.

Prepared By:

Brian R. Bowman, 8/12/03
Quality Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2003

Mr. Brian R. Bowman
Quality Manager
AmeriWater
1257 Stanley Avenue
DAYTON OH 45404

Re: K021560
Trade/Device Name: AmeriWater® Purification System for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: May 15, 2003
Received: May 16, 2003

Dear Mr. 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.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

AmeriWater®

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510 (K) Number: K021560

Device Name: The AmeriWater Purification System For Hemodialysis

STATEMENT OF INTENDED USE

The AmeriWater Purification System for Hemodialysis is used to remove organic and inorganic substances and microbial contaminants from water. Purified (or treated) water will then be used to prepare and dilute dialysate concentrate to form dialysate and/or rinse dialyzers for multiple-use dialyzers. AmeriWater does not recommend nor endorse any other use for water treated with AmeriWater systems. AmeriWater further does not endorse any specific hemodialysis or reprocessing procedures or equipment.

*Note: Federal Law restricts this device to sale by or on the order of a physician for use as a water treatment device for hemodialysis.

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021560

Prescription Use √