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SUMMARY STATEMENT

K 991519
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With regard to AmeriWater's 510(k) submission to the FDA, (ref. K991519)
The AmeriWater Purification System for Hemodialysis is a water purification system designed and maintained to produce water of quality that consistently meets or exceeds AAMI Standards for water used in Hemodialysis and/or Dialyzer reuse. It is AmeriWater's contention that the system is substantially equivalent to the Reverse Osmosis Water Purification System; Continental Water Systems Corp. (K894300) and other systems currently legally marketed in the U.S. The components may include all or some of the following:

Tempering valve	Float & Pressure Control
Temperature Gauge	Return Flow Diffuser
Backflow Preventor	Storage Vessel
Pressure Gauges	Repressurization Pump(s)
Booster Pump	Deionization
Multi Media Filtration	Submicron Filtration
Carbon Filtration	Distribution System
Water Softener	PVC Pipe & Fittings
Automatic Lockout	PVC ball valves
5 micron prefilter	PVC labcock valves
Reverse Osmosis	System Alarms

System design is determined by the design team following collection of information from the Customer Survey of Requirements, and complete chemical analysis of the waters to be treated. The system is complete with monitors and audible & visual 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 day support to all owner facilities for the life of the equipment.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sandra E. Monsman
Dialysis Specialist
AmeriWater®
1257 Stanley Avenue
Dayton, OH 45404

Re: K991519
AmeriWater Water Purification system
for hemodialysis
Dated: January 21, 2000
Received: January 24, 2000
Regulatory Class: II
21 CFR 876.5665/Procode: 78 FIP

Dear Ms. Monsman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsma.main.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

