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August 16, 2005

AmeriWater®

1303 Stanley Avenue Dayton, Ohio 45404
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Subject: 510 (K) SUMMARY

510 (K) Number:	K051031
AmeriWater Contact:	Brian R. Bowman, Quality Manager
Proprietary Name:	AmeriWater Solution Mix and Distribution System for Hemodialysis
Common Name:	Mixing and distribution system for bicarbonate and acid concentrates for hemodialysis.
Classification Name:	Tank, Holding, Dialysis and Accessories
Classification:	Class II Medical Device under §876.5665 Panel: Gastroenterology Product Code: FIN

Intended Use: The AmeriWater Solution Mix and Distribution System for Hemodialysis is intended to be used in a hemodialysis facility to mix and deliver, to the point(s) of use, bicarbonate and acid solutions necessary for hemodialysis. Federal law restricts this device to sale by or on the order of a physician for use in hemodialysis applications

Device Description: The AmeriWater Bicarb Mix and Distribution System utilizes purified water from the dialysis facility's water purification system to mix bicarbonate solution and to distribute the solution to the point(s) of use. The system features automatic fill and mix, high vortex pumped mixing action, lightly pressurized distribution, and complete and efficient disinfection. A single tank system, the AmeriWater Solution Mixing System, is also available to mix solutions from concentrate.

The AmeriWater Acid Concentrate Distribution System is used to store and distribute the acid concentrate(s) required for hemodialysis to the point(s) of use. Solution stored in and distributed by the Acid Concentrate Distribution System is mixed prior to being transferred to the system. Lightly pressurized distribution and recirculation provides steady, consistent delivery.

AmeriWater Wall Boxes are recessed boxes located at the point(s) of use that are intended to provide acid, bicarb, and/or water connections compatible with the dialysis machines used in the hemodialysis facility. Wall boxes are available in several configurations to accommodate most dialysis applications. Customer-supplied dialysis machine fittings are professionally installed by AmeriWater.

Statement of Substantial Equivalence: The AmeriWater Solution Mix and Distribution System for Hemodialysis is substantially equivalent in intended use, function, and technology to the Better Water Central Concentrate Delivery System for Dialysis, Central Bicarbonate Mixing/Delivery System (K992793).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

Mr. Brian R. Bowman
Quality Manager
AmeriWater®
1303 Stanley Avenue
DAYTON OH 45404

Re: K051031
Trade/Device Name: AmeriWater Solution Mix and Distribution System for Hemodialysis
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FIN
Dated: November 23, 2005
Received: November 28, 2005

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known) **K051031**

Device Name: AmeriWater Solution Mix and Distribution System for Hemodialysis

Indications For Use: The AmeriWater Solution Mix and Distribution System for Hemodialysis is intended to be used in a hemodialysis facility to mix and deliver, to the point(s) of use, bicarbonate and acid solutions necessary for hemodialysis. Federal law restricts this device to sale by or on the order of a physician for use in hemodialysis applications

AmeriWater Bicarb Mix and Distribution System, Models 00BC55-55, 00BC100-100, and 00BC100-200 (Dual Tanks): The AmeriWater Bicarb Mix and Distribution System for Hemodialysis is intended to be used in a hemodialysis facility to mix and deliver, to the point(s) of use, bicarbonate solutions necessary for hemodialysis. Federal law restricts this device to sale by or on the order of a physician for use in hemodialysis applications.

AmeriWater Solution Mixing System, Model 00BC100 (Single Tank): The AmeriWater Solution Mixing System is intended to be used in a hemodialysis facility to mix and deliver, to the point(s) of use, bicarbonate and acid solutions necessary for hemodialysis. Federal law restricts this device to sale by or on the order of a physician for use in hemodialysis applications.

AmeriWater Acid Concentrate Distribution System, Models 00AS130, 00AS300, and 00AS500: The AmeriWater Acid Concentrate Distribution System is intended to be used in a hemodialysis facility to store and deliver, to the point(s) of use, acid concentrates necessary for hemodialysis. Federal law restricts this device to sale by or on the order of a physician for use in hemodialysis applications.

AmeriWater Wallboxes for Dialysis: The AmeriWater Wallbox for Dialysis is intended to be used in a hemodialysis facility as the point of use connection for purified water, bicarbonate, and acid solutions necessary for hemodialysis. Federal law restricts this device to sale by or on the order of a physician for use in hemodialysis applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

David A. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051031