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Anderson, SC 29624  
Phone: (864) 375-0105  
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APR 1 0 2000

K993272  
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510(k) Summary

**Submitter Information:**

Company Name: Pure Water, Inc.  
Company Address: 305 W. Market St.  
Anderson, SC 29624  
Company Phone: (864) 375-0105  
Company Fax: (864) 226-1384  
Contact Person: Rhonda S. McCoy  
Prepared: September 27, 1999

**Trade Name:** Pure Water, Inc.'s Bicarb Mix, Storage and Distribution System

**Classification Name:** Bicarb Mix, Storage and Distribution System for Hemodialysis

**Equivalency:** Pure Water, Inc.'s Bicarb Mix, Storage and Distribution System is substantially equivalent to Better Water's Water Purification System for Hemodialysis (510(k) #: K920186) and ZyzaTech Water System, Inc.'s Water Purification Systems and Components and Portable Reverse Osmosis Systems (510(k) #: K964539), which are currently in commercial distribution.

**Device Description:** Pure Water, Inc.'s Bicarb Mix, Storage and Distribution System uses Reverse Osmosis, provides for batch mixing of Bicarb liquid concentrate, transfer to storage and delivery to point of use.

The Bicarb Mix Tank allows Bicarb liquid concentrate to be mixed in batches then transferred to a Storage Tank.

The Storage and Distribution components of the system serve to deliver Bicarb liquid concentrate to the point of use.

Pure Water, Inc.'s Bicarb Mix, Storage and Distribution System can be customized to best meet the needs of the user.

Pure Water, Inc.'s Bicarb Mix, Storage and Distribution System meets or exceeds all Association for the Advancement of Medical Instrumentation (AAMI) National Standards for Hemodialysis.



APR 10 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Ms. Rhonda S. McCoy  
Office Manager  
Pure Water, Inc.  
305 W. Market Street  
Anderson, SC 29624Re: K993272  
Pure Water, Inc.'s Bicarb Mix, Storage  
and Distribution System  
Dated: January 19, 2000  
Received: January 24, 2000  
Regulatory Class: II  
21 CFR §876.5820/Procode: 78 FIN and KPO

Dear Ms. McCoy:

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/dsmamain.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)

## INDICATIONS FOR USE STATEMENT

The Pure Water, Inc.'s Bicarb Mix, Storage and Distribution system is intended to be used in Hemodialysis facilities for the mixing, storage and distribution of Bicarb liquid concentrate to be used in the treatment of Hemodialysis patients.



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(Division Sign-Off)  
Division of Reproductive, Abdominal, **ENT**,  
and Radiological Devices  
510(k) Number K993272