JAN 24 2000

305 W. Market Street
Anderson, SC 29624
Phone: (864) 375-0105
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K992786 p.1/1

510(k) Summary

Submitter Information:

Company Name:	Pure Water, Inc.
Company Address:	305 West Market Street Anderson, South Carolina
Company Phone:	(864) 375-0105
Company Fax:	(864) 226-1384
Contact Person:	Rhonda S. McCoy
Prepared:	August 17, 1999

Trade Name: Pure Water, Inc. Water Purification System

Classification Name: Water Purification System for Hemodialysis

Equivalency: The Pure Water, Inc. Water Purification 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: The Pure Water, Inc. Water Purification System uses Reverse Osmosis technology to produce pure water. Reverse Osmosis utilizes a semi-permeable membrane and high hydrostatic pressure.

Pretreatment is used for the purpose of removing elements present in the source water that can damage the RO membranes.

The storage and distribution components of the system serves to deliver pure water produced by the RO to the point of use.

The Pure Water, Inc. Water Purification System can be customized to best meet the water needs of the user.

The Pure Water, Inc. Water Purification System meets or exceeds all Association for the Advancement of Medical Instrumentation (AAMI) National Standards for Hemodialysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2000

Ms. Rhonda S. McCoy
Office Manager
Pure Water, Inc.
305 West Market Street
Anderson, South Carolina 29624

Re: K992786
Pure Water, Inc. Water Purification System
Dated: November 23, 1999
Received: November 26, 1999
Regulatory Class: II
21 CFR §876.5665/Procode: 78 FIP

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) 594-4613. 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"(21 CFR 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992786

Device Name: Pure Water, Inc. Water Purification System for Hemodialysis

Indications For Use:

The Pure Water, Inc. Water Purification System is intended to be used in Hemodialysis facilities for the purification of water to be used to dilute dialysate concentrate and in the reprocessing of dialyzers for reuse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992786

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)