K072158 – 510(k) Pre-market Notification
D.I. Exchange Tanks for Dialysis

510(k) Summary

1. **Submitter:** Aqua Pure
Staubach Barror Water systems Inc. FEB 21 2008
495 Rotterdam Ind. Park
Schenectady, NY 12306

Contact Person: Jarrod Staubach
V.P. / Quality Manager
Tel:(518)355-4390

Date prepared: November 26, 2007

2. **Device name:** D.I. Exchange Tanks for Dialysis.

3. **Device Classification:** Class II Medical Device under 21 CFR §876.5665

4. **Predicate Device:** Ameriwater Dialysis Deionizer Exchange Tanks

5. **Device Description:** Aqua Pure's D.I. Exchange Tanks for Dialysis are FRP tanks filled with mixed bed resin. Widget connectors are used in conjunction with a machined PVC schedule 80 head, stand pipe, fill port, and distributor basket. Our tanks are designed to supply AAMI standard water for dialysis through ion exchange. The D.I. exchange tanks are based on the Ameriwater Dialysis Deionizer Exchange Tanks K991519.

6. **Indications for use:** The Aqua Pure DI exchange tanks are used according to current AAMI standards (RD 62) and are intended to supply dialysis grade water, for use in dialysis, concentrate preparation systems, dialyzer reuse systems and rinsing of sterilants. The exchange tanks can be used for either primary water purification or to supply emergency backup water purification for dialysis units. The D.I. exchange tanks for dialysis are only one part of a complete water treatment system and must be used in conjunction within a water treatment system with appropriate pre-treatment and post-treatment.

7. **Comparison with predicate device:** Aqua Pure's D.I. Exchange Tanks for Dialysis are substantially equivalent to the currently marketed Ameriwater Dialysis Deionizer Tanks, and have not altered the fundamental scientific technologies or materials used in the predicate device. The intended use of the D.I. Exchange Tanks for Dialysis is the same as the intended use of the predicate device K991519.

Tank parts and manufacturers.	**Ameriwater Dialysis Deionizer Exchange Service**	**Aqua Pure D.I. Exchange Tanks for Dialysis**
Tank type and manufacturer	FRP tanks manufactured from Park International	FRP tanks manufactured from Park International
Resin type and manufacturer	MBD-10 Resin manufactured by ResinTech	MBD-10 Resin manufactured by ResinTech
Audio alarm type	Resi-Lite 1 megohm audio/visual alarm positioned between worker and polisher	Resi-Lite 1 megohm audio/visual alarm positioned between worker and polisher
Interconnecting tubing	High purity PVC interconnecting tubing	High purity PVC interconnecting tubing
Connectors	Widget connectors made of glass filled Noryl	Widget connectors made of glass filled Noryl
Heads and fill plugs	PVC schedule 80 machined head with PVC schedule 80 fill plug.	PVC schedule 80 machined head with PVC schedule 80 fill plug.
Stand pipe and distributor baskets	PVC schedule stand pipe and distributor basket.	PVC schedule stand pipe and distributor basket.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Mr. Jarrod J. Staubach
Vice President/Quality Manager
Staubach Barror Water Systems, Inc.
(DBA: Aqua Pure)
495 Rotterdam Industrial Park
SCHENECTADY NY 12306

Re: K072158
Trade/Device Name: D.I. Exchange Tanks for Dialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: January 2, 2008
Received: February 5, 2008

Dear Mr. Staubach:

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 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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: K072158

Device Name: D.I. Exchange Tanks for Dialysis

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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)

(vers 6/25/05)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072158