AQUA SYSTEMS

♦Commercial And Industrial Water Solutions♦

APR - 2 2010

April 2, 2010

## 510(k) Summary

1. ***Submitter***: New Aqua LLC (dba Aqua Systems)
114 Vista Parkway
Avon, Indiana, 46123

**Contact**: Nevin Rudie
Commercial Industrial Director
Telephone: 317-272-6715

Date Prepared: March 19, 2010

2. ***Device Name***: Deionizer and Carbon Exchange Tanks for Dialysis

3. ***Device Classification***: Class II Medical Device under 21 CFR §876.56653.

4. ***Predicate***: AmeriWater Dialysis Deionizer Exchange Tanks

5. ***Device Description:*** New Aqua LLC Deionizer and Carbon Filter exchange tanks for Dialysis are FRP tanks filled with high purity DI resins for the Deionizers and acid washed carbon for the carbon filters. Union style connectors are used in conjunction with a molded Noryl head, PVC riser pipe and distributor basket. The tanks are designed to supply AAMI standard water for dialysis through ion exchange. The tanks are based on the AmeriWater Dialysis Deionizer Exchange Tanks K991519.

6. ***Indications for use:*** The Deionizer and Carbon Exchange Service for Hemodialysis are intended to be used in a hemodialysis facility according to AAMI standards to supply purified water for use in hemodialysis applications per the requirements of ANSI/AAMI RD62. The exchange tanks can be used for either primary water purification or to supply emergency backup water purification for dialysis. These exchange tanks are components of a larger water treatment system employing adequate pretreatment and post treatment sections. These tanks are not to be used alone.
Upon exhaustion, these tanks will be replaced with other Deionization Tanks containing newly regenerated resin or with new resin altogether, or in the case of Carbon Tanks, with tanks containing fresh virgin carbon.

7. ***Comparison with Predicate Device:*** New Aqua LLC exchange tanks for dialysis are substantially equivalent to the currently marketed AmeriWater Dialysis tanks and have not altered the fundamental scientific technologies used in the predicate device. The intended use of the exchange tanks for dialysis is the same as the intended use of the predicate device K991519.

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| Tank Parts & Manufacturer | AmeriWater Dialysis Deionizer Exchange Service | New Aqua LLC Deionizer Exchange Service |
|---|---|---|
| Tank Type & Manufacturer | FRP tanks manufactured by Park International * | FRP tanks manufactured by Park / Pentair |
| Resin Type & Manufacturer | MBD-10 Resin by ResinTech | MBD-15 Resin by ResinTech |
| Carbon Type & Manufacturer | Calgon Centaur | Calgon CPGLF |
| 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 | Union style connectors made of glass filled Noryl |
| Heads and fill plugs | PVC schedule 80 machined head with PVC schedule 80 fill plug | Glass filled Noryl head and fill plug |
| Stand pipe and distributor baskets | PVC schedule stand pipe and distributor basket | PVC schedule stand pipe and distributor basket |

*Park International is now owned by Pentair Water Treatment. Tanks are sold under the names Structural and Park.

Note: All components used meet or exceed ANSI/AAMI RD62-2006 standards.

8. ***Differences:*** There minor differences between the predicate and New Aqua LLC devices. These differences are within the Resin and Carbon types selected. The predicate device uses ResinTech MBD-10 while the New Aqua LLC device uses MBD-15. The difference between the two is the predicate device uses ResinTech Anion type 1 resin media while the New Aqua LLC device uses ResinTech Anion type 1P resin media. The type 1P has improved cleaning performance allowing greater consistency in cleaning during regeneration providing greater performance and improved consistant gallonage thru put making the type 1P a superior product. The carbon Medias again are from the same manufacturer. The predicate device uses Calgon's Centaur while the New Aqua LLC device uses Calgon's CPGLF. Both medias meet AAMI RD62 2006 standards.

9 ***Performance Testing***

A system performance test was run by simulating operational conditions. A system consisting of Carbon, and DI resins was set in place and operated. Quality testing of chlorine, chloramine and resistivity levels were monitored to ensure performance.

To qualify performance four (4) water samples were taken for validation purposes. Two samples of the raw feed water were drawn for use as a beginning foundation of the need for treatment. Two samples were taken from the final DI unit to validate performance meeting AAMI RD62 standards.

The water samples were sent to two separate labs. To test for AAMI standards a raw water feed sample and a treated water feed sample was sent to AmeriWater. To test for TOC a raw water feed sample and a treated water feed sample was sent to Broward Testing Laboratory, LTD.

Analysis results from AmeriWater show AAMI standard performance. Results from Broward Testing Laboratory, LTD show a reduction of TOC to non detectable limits.

Analysis results and testing facility contacts are included in Section 10 of this submittal.

10 **Conclusions**

Performance testing demonstrates that the exchange tank devices perform to the same standard as that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Mr. Nevin Rudie
Commercial/Industrial Director
New Aqua LLC (dba Aqua Systems)
7785 East U.S. Hwy 36
AVON IN 46123

APR - 2 2010

Re: K092481
Trade/Device Name: Deionizer and Carbon Exchange Service for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: March 19, 2010
Received: March 26, 2010

Dear Mr. Rudie:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting 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 K092481:

Device Name: Deionizer and Carbon Exchange Service for Hemodialysis

Indications for Use: The Deionizer and Carbon Exchange Service for Hemodialysis are intended to be used in a hemodialysis facility according to AAMI standards to supply purified water for use in hemodialysis applications per the requirements of ANSI/AAMI RD62. The exchange tanks can be used for either primary water purification or to supply emergency backup water purification for dialysis. These exchange tanks are components of a larger water treatment system employing adequate pretreatment and post treatment sections. These tanks are not to be used alone.

Upon exhaustion, these tanks will be replaced with other Deionization Tanks containing newly regenerated resin or with new resin altogether, or in the case of Carbon Tanks, with tanks containing fresh virgin carbon.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092481