AQUA Sciences Inc.
A Pure Splash of Innovation

510(k) Submission

FEB - 3 2011

510(k) Summary
Carbon and Mixed Bed Deionization (DI) Exchange Tanks

Date Prepared: September 20, 2010

Prepared/Submitted by:
Aqua Sciences, Inc.
565 Fillmore Avenue
Tonawanda, New York 14150

Contact Person:
Mr. Michael J. Todd
Quality Manager
(716) 695-1200

Device Name:
Deionization Exchange Tanks
Carbon Exchange Tanks

Device Classifications:
Water Purification Component
Class II Medical Device
21 CFR §876.5665, Product Code – FIP

Predicate Device: AmeriWater Purification System for Hemodialysis (K991519)

Model Numbers:

Deionizing Tank Model No.	Carbon Tank Model No.
AS-618-MB-D	AS-618-GAC
AS-818-MB-D	AS-818-GAC
AS-844-MB-D	AS-844-GAC
AS-1047-MB-D	AS-1047-GAC
AS-1447-MB-D	AS-1447-GAC

Device Description:

Aqua Sciences, Inc. Mixed Bed Deionization Exchange Tanks (DI) are Fiberglass Reinforced Polypropylene (FRP) tanks filled with mixed bed deionizing resin. The tank sizes are common for the Dialysis industry with similar inlet and outlet fittings, PVC heads and tank distributors. The DI Exchange Tanks are dedicated for ion exchange resin only. Our tanks are designed to deliver Association for the Advancement of Medical Instrumentation (AAMI) standard water through an ion exchange process.

Aqua Sciences, Inc. Carbon Exchange Tanks are Fiberglass Reinforced Polypropylene (FRP) tanks filled with new activated carbon. The tank sizes are common for the Dialysis industry with similar inlet and outlet fittings, PVC heads and tank distributors. The Carbon Exchange Tanks are dedicated for carbon only and used to remove chlorine and chloramines.

[510(k) summary continued]

Indication of Use: The ASI Deionizer and Carbon Exchange Tank Service for hemodialysis are intended to be used in a hemodialysis facility according to ANSI/AAMI-RD62:2006 standards to supply purified water for use in hemodialysis. These exchange tanks are components of a larger water treatment system employing adequate pretreatment and post treatment sections. These exchange 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 new virgin carbon. Federal law restricts this device to sale by or on the order of a physician for use in hemodialysis applications.

Comparison to Predicate: AmeriWater Exchange Tanks (K991519)

Deionization Exchange tanks from both Aqua Sciences, Inc. and AmeriWater are utilized to remove positive and negative charged dissolved solids and salts from the water. Both companies utilize mixed bed resins consisting of cation and anion resin.

Activated Carbon Filtration is utilized by both Aqua Sciences, Inc. and AmeriWater to remove chlorine and chloramines from the feed water. Aqua Sciences, Inc. uses carbon in accordance with AAMI current standards. Both companies use two (2) carbon filters in series configuration. Aqua Sciences, Inc. and AmeriWater both use granular activated carbon with a minimum iodine number of 900. Both companies recommend a chlorine and chloramines water test before each patient shift.

Summary: The Aqua Sciences, Inc. water purification components and the AmeriWater predicate device components are substantially equivalent to one another. All the water purification components and technology in this submission are comparable. In addition, nonclinical tests were conducted on product water from a replicated intended exchange tank configuration. Results verify product complies with AAMI RD:62 Standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Michael J. Todd
Quality Manager
AQUA Sciences, Inc.
565 Fillmore Avenue
TONAWANDA NY 14150

FEB - 3 2011

Re: K102892
Trade/Device Name: Aqua Sciences, Inc. (ASI) Deionizer and Carbon Exchange Tank Service for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: January 12, 2011
Received: January 21, 2011

Dear Mr. Todd:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use (revised)

510 (k) Number: K102892

Device Name: Aqua Sciences, Inc. (ASI) Deionizer and Carbon Exchange Tank Service for Hemodialysis

Indications for Use: The ASI Deionizer and Carbon Exchange Tank Service for hemodialysis are intended to be used in a hemodialysis facility according to ANSI/AAMI-RD62:2006 standards to supply purified water for use in hemodialysis. These exchange tanks are components of a larger water treatment system employing adequate pretreatment and post treatment sections. These exchange 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 virgin carbon. 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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102892