JUL 10 2009

Pre-Market Notification 510(K) Summary

Water Purification Components for Hemodialysis

Date	December 4, 2008
Prepared/Submitted By	DiPure, LLC DiPure Water Technologies 1919 Edwards Street Houston, Texas 77007
Contact	Tim Marco President/General Manager 713.686.4049
Device Name	Carbon and DI Exchange Tanks for Hemodialysis
Device Classification	Class II Medical Device, 21 CFR 876.5665 Product Code 78 FIP
Predicate Device	AmeriWater Dialysis Deionizer and Carbon Exchange Tanks Registration Number K991519
Device Description	DiPure's DI Exchange Tanks for Dialysis are approved tanks filled with mixed bed resin. 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 DI exchange tanks are based on the Ameriwater Dialysis Deionizer Exchange Tanks. DiPure's Carbon Exchange Tanks for Dialysis are approved tanks filled with activated carbon. Connectors are used in conjunction with a machined PVC schedule 80 head, stand pipe, fill port, and distributor basket. These tanks are designed to remove chlorine and chloramines. These tanks are based on the Ameriwater Carbon Exchange Tanks.

Indications for Use	The DiPure Deionization Tanks are exchangeable/rechargeable mix bed tanks intended to remove ions from the water to a sufficient level to allow safe treatment of Hemodialysis patients. These deionization tanks are not to be used alone, but are intended to be a part of a larger water treatment system employing adequate pre-treatment and post-treatment. Upon exhaustion, these tanks will be replaced with other tanks containing newly regenerated resin, or new resin altogether. The DiPure Carbon Exchange Tanks are activated carbon tanks intended to remove chlorine and chloramines from the water to allow safe treatment of Hemodialysis patients. These carbon tanks are not to be used alone, but are intended to be a part of a larger water treatment system employing adequate pre-treatment and post-treatment. Upon exhaustion, these tanks are replaced with other tanks containing new activated carbon.
Comparison to Predicate AmeriWater Device	Deionization tanks from both DiPure and AmeriWater are utilized to remove dissolved solids from the water. Both utilize mixed bed resins, consisting of cation and anion resins to remove the charged particles in the water. Both utilize parts and materials that are NSF and/or FDA approved. Activated carbon filtration is utilized by both DiPure and AmeriWater to filter out chlorine and chloramines from the water. DiPure uses carbon filter made from materials that are NSF and/or FDA approved. Both companies use two (2) carbon filters in a series configuration. Both DiPure and AmeriWater recommend the chlorine and chloramines are checked before each patient shift. Both companies utilize an activated carbon with an iodine number of 900 or greater. DiPure always recommends using dual carbon filters in series in every dialysis water system installed, including single patient systems.

In Summary, the DiPure water purification components and the AmeriWater predicate device components are substantially equivalent to one another. The core water purification components and technology are exactly the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2009

Mr. Tim Marco
President/General Manager
DiPure, LLC
DiPure Water Technologies
1919 Edwards Street
HOUSTON TX 77007

Re: K083712
Trade/Device Name: Carbon and Deionized Exchange Tanks for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: June 22, 2009
Received: June 25, 2009

Dear Mr. Marco:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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: **K083712**

Device Name: *Carbon and Deionized Exchange Tanks for Hemodialysis*

Indications for Use:

The DiPure Deionization Tanks are exchangeable/rechargeable mix bed tanks intended to remove ions from the water to a sufficient level to allow safe treatment of Hemodialysis patients. These deionization tanks are not to be used alone, but are intended to be a part of a larger water treatment system employing adequate pre-treatment and post-treatment. Upon exhaustion, these tanks will be replaced with other tanks containing newly regenerated resin, or new resin altogether.

DiPure Deionization Tank Model Numbers:

DMB025 - .25 cu ft Deionization Tank
DMB05 – .5 cu ft Deionization Tank
DMB12 – 1.2 cu ft Deionization Tank
DMB20 – 2.0 cu ft Deionization Tank
DMB36 – 3.6 cu ft Deionization Tank

The DiPure Carbon Exchange Tanks are activated carbon tanks intended to remove chlorine and chloramines from the water to allow safe treatment of Hemodialysis patients. These carbon tanks are not to be used alone, but are intended to be a part of a larger water treatment system employing adequate pre-treatment and post-treatment. Upon exhaustion, these tanks are replaced with other tanks containing new activated carbon.

DiPure Carbon Tank Model Numbers:

DAC025 - .25 cu ft Carbon Tank
DAC05 - .5 cu ft Carbon Tank
DAC12 – 1.2 cu ft Carbon Tank
DAC20 – 2.0 cu ft Carbon Tank
DAC 36 – 3.6 cu ft Carbon Tank

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K083712