K983512

4/28/99

510K SUMMARY

Water Vault Corporation
2003 Blair Blvd
Nashville, TN 37212
615-292-7336
Contact: Michael Peterson

Water Vault Cube, Watertreatment System for Hemodialysis
Class II Device

Legally Marketed Predicate Device - MARCOR Water Treatment System For Hemodialysis K#945559

	Water Vault Inc.	**Predicate Device** MARCOR #K945559
INTENDED USE	Hemodialysis	Hemodialysis
EQUIPMENT:	Makes Use Of Existing FDA Cleared Reverse Osmosis Unit Pretreatment Equipment Sized Based upon water analysis And RO Mfg. Requirements	Makes Use Of Existing FDA Cleared Reverse Osmosis Unit Pretreatment Equipment Sized Based upon water analysis And RO Mfg. Requirements
SAFETY FEATURES:	Makes Use Of Existing Features Incorporated in Design of RO Unit	Makes Use Of Existing Features Incorporated in Design of RO Unit
WATER CONTACT MATERIALS:	FDA NSF Compliant	FDA NSF Compliant
PERFORMANCE SPECIFICATIONS:	Delivery Of Specified Quantity Of AAMI Standard Quality	Delivery Of Specified Quantity Of AAMI Standard Quality
CAPACITY:	Determined By RO Capacity	Determined By RO Capacity

How The Device Works:
Organic, inorganic and microbial contaminants are removed from water supplied to hemodialysis clinics for use in the dilution and preparation of dialysate solutions used in hemodialysis machines. The water treatment system includes a means of tempering the water and pretreatment, followed by reverse osmosis, ultrafiltration and UV sterilization. Pretreatment includes water softening to remove hardness and Granular Activated Carbon treatment to remove Chlorine and Chloramines in addition to filament cartridge filters to control particulate solids. Reverse Osmosis utilizes a pressure gradient to reverse the process water diffusion across a semipermeable membrane, concentrating the contaminants which are subsequently rejected as concentrate. Water forced through the membrane known as "Permeate" is then passed through a hollow fiber ultra filter to remove microorganisms, pyrogens and endotoxins. A UV light source that provides a minimum of 30,000 microwatts/cm2 sec limits further bacterial growth in the treated water.

5 1 OK SUMMARY

Nonclinical Test Results:

The following sample results were taken from tests of a demonstration unit using an Osmonics Solo$_{TM}$ reverse osmosis unit Serial Number 96-61650-11

Component	Feed Water mg/l	Permeate mg/l	AAMI Standard mg/l	Meets or Exceeds AAMI Standard
Calcium	34.3	1	2	Yes
Magnesium	5.63	1	4	Yes
Sodium	5.68	1	70	Yes
Potassium	1.55	1	8	Yes
Fluoride	0.82	0.1	0.2	Yes
Chlorine	1.68	0.02	0.5	Yes
Chloramines	0.02	0.02	0.1	Yes
Nitrate	0.37	0.1	2	Yes
Sulfate	28.8	5	100	Yes
Copper	0.105	0.01	0.1	Yes
Barium	0.022	0.01	0.1	Yes
Zinc	0.115	0.02	0.1	Yes
Aluminum	0.221	0.01	0.01	Yes
Arsenic	0.005	0.005	0.005	Yes
Lead	0.101	0.003	0.005	Yes
Silver	0.005	0.005	0.005	Yes
Cadmium	0.001	0.001	0.001	Yes
Chromium	0.005	0.005	0.014	Yes
Selenium	0.005	0.005	0.05	Yes
Mercury	0.0002	0.0002	0.0002	Yes

Based upon the above water assay, the water produced meets or exceeds AAMI standards for water to be used in the preparation of dialysate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 1999

Michael J. Peterson, P.E.
President
Water Vault, Inc.
2003 Blair Boulevard
Nashville, Tennessee 37212

Re: K983512
Water Vault Cube
Dated: February 9, 1999
Received: February 10, 1999
Regulatory class: II
21 CFR §876.5665/Product code: 78 FIP

Dear Mr. Peterson:

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): K983512

Device Name: WaterVault Cube, Water Treatment System for HemoDialysis

Indications For Use:

The WaterVault Cube Water Treatment System for HemoDialysis is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983512/S002