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K993877
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NELSON ENVIRONMENTAL
TECHNOLOGIES, INC.

Water Quality Association
MEMBER

SUMMARY OF SAFETY & EFFECTIVENESS

1999 November 10

1. Submitter: Nelson Environmental Technologies, Inc.
   301-E N. McColl Rd.
   McAllen, TX 78501
   Contact: Burke A. West, P.E., CWS-VI
   956-618-0375 telephone
   956-618-4330 fax

2. Device Classification Name: Water Purification System for Hemodialysis

3. Substantial Equivalence: Zyzatech Water Systems, Inc.
   Water Treatment System for Hemodialysis
   510(k)#K964539

4. Device Description:

The water purification system is a complete system accepting the influent facility water and providing purified water meeting AAMI standards for hemodialysis use. It removes organic, inorganic, and microbial contaminants from the water.

The heart of the system includes carbon filters along with a reverse osmosis (RO) unit and/or portable exchange (PE) mixed-bed (MB) deionization (DI) tanks along with appropriate alarms. This equipment removes the oxidants such as chlorine and chloramines and mineral salts (dissolved solids) from the water. The specific configuration of the equipment will depend upon the customer's water quality desires (specifications) beyond the minimum AAMI standards.

Pretreatment is used before the RO unit to match the specific influent water quality to those needs of the RO unit and/or final water specifications. Pretreatment can include pressure boosting, sediment and colloidal material filtration, water softening, pH balancing and specific element or compound reduction such as iron.

The system usually includes a storage tank that is conical-bottomed and sealed. It has an air-filtered vent, checked over-flow, level switches and sprayer. Repressurizing pump(s) are used to deliver the water to the hemodialysis system.

Deionization is used either to polish the RO water or to remove total dissolved solids (TDS) from the influent water. The latter will occur either in emergency conditions when an RO is being used in the system and it is being by-passed or as an alternative

to an RO unit. When PE MB DI tanks are used, two tanks are always used with resistivity indicators/alarms following each one. Then following the tanks are a resin trap, sub-micron filter(s), and optionally a shut-down valve and ultraviolet (UV) disinfection.

The system is self-monitored and alarms are activated when operator attention is needed. Pressure gauges and sample ports are strategically placed throughout the system for system performance monitoring. A conductivity monitor/controller is placed in sight of the nurses' station. Its probe is located at the end of the watertreatment system. Alarms at site and/or remotely located near the nurses' station sound when an alarm condition exists with the RO unit, the water level in the tank drops to a pre-set level, the conductivity at the exit of the watertreatment system exceeds the pre-set level, and if PE MB DI tanks are used, the outlet resistivity falls below the pre-set limit.

3. Intended Use Statement:

Nelson Water Treatment Systems' Water Treatment System for Hemodialysis is intended to be used for purifying the water used in hemodialysis treatment by removing organic, inorganic, and microbial substances. When used as a medical device, Federal Law restricts this device to sale by or on the order of a physician.

4. Technological Characteristics Compared to the predicate Device

Predicate Device is Zyzatech Water Treatment System for Hemodialysis 510(k)#K964539

Item	**Nelson Environmental Technologies, Inc.**	**Zyzatech Water Systems, Inc.**
Intended use	Hemodialysis Treatment	Hemodialysis Treatment
Equipment	Incorporates FDA-certified RO unit	Incorporates FDA-certified RO unit
Pre-treatment Stage	Designed based upon water analysis, RO manufacturer's requirements, and AAMI specifications	Designed based upon water analysis, RO manufacturer's requirements, and AAMI specifications
Water Contact Materials	FDA NSF Compliant	FDA NSF Compliant
Safety Features	Utilizes RO safety features Water conductivity/resistivity self-monitored and alarmed Tank water self-monitored and alarmed Remote alarms at Nurses' Station	Utilizes RO safety features Water conductivity/resistivity self-monitored and alarmed Tank water self-monitored and alarmed Remote alarms at Nurses' Station
Performance	Meets or exceeds AAMI	Meets or exceeds AAMI

	Standards	Standards

5. Conclusions of Performance Data

The following data was obtained from an installation in Houston meeting the design specifications of the proposed system.

Component	Feed Water mg/L	Permeate mg/L	AAMI Standard mg/L	Meets or Exceeds AAMI Standard
Calcium	341.3	0.144	2	Yes
Magnesium	3.5	0.002	4	Yes
Sodium	37.2	2.6	70	Yes
Potassium	4.2	0.025	8	Yes
Fluoride	0.0	0.0	0.2	Yes
Chlorine	0.15	0.0	0.5	Yes
Chloramines	0.35	0.0	0.1	Yes
Nitrate	0.4	0.0	2	Yes
Sulfate	37.7	0.0	100	Yes
Copper	0.043	0.000	0.1	Yes
Barium	0.061	0.0005	0.1	Yes
Zinc	0.026	0.024	0.1	Yes
Aluminum	0.107	0.0005	0.01	Yes
Arsenic	0.001	0.000	0.005	Yes
Lead	0.002	0.0001	0.005	Yes
Silver	0.000	0.00009	0.005	Yes
Cadmium	0.00001	0.000	0.001	Yes
Chromium	0.005	0.000	0.014	Yes
Selenium	0.001	0.000	0.05	Yes
Mercury	0.0001	0.0002	0.0002	Yes

Thus, based upon the above results taken from a system after 48 hours of residence time in system, the water produced and stored meets or exceeds AAMI standards for Hemodialysis treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2000

Burke A. West, P.E., CWS-VI
President
Nelson Environmental Technologies, Inc.
301-E N. McColl Road
McAllen, TX 78501

Re: K993877
Water Purification System for Hemodialysis
Dated: March 21, 2000
Received: March 23, 2000
Regulatory Class: II
21 CFR §876.5665/Procode: 78 FIP

Dear Mr. West:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) NUMBER (IF KNOWN): K993877

DEVICE NAME: Water Purification System for Hemodialysis

INDICATIONS FOR USE:

Nelson Water Systems' Water Purification for Hemodialysis is intended to be used for purifying the water used in hemodialysis treatment. It removes organic, inorganic, and microbial contaminants from the water.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993877