MAY - 3 2000

Section 5
Summary of Safety & Effectiveness

H2Only Complete Water Purification System
for Hemodialysis

submitted by
Serv-A-Pure Company
1101 Columbus Ave.
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Contact: Richard Herzberger
September 16, 1999

Common or Classification Name: Complete Water Purification System for Hemodialysis

Proprietary Name: H2Only Complete Water Purification System for Hemodialysis

Claiming substantial equivalence to:

U.S.Filter Company, (800) 466-7873	
Water Treatment System for Hemodialysis	K980182
Osmonics Inc., (612) 933-2277	
Water Treatment System for Hemodialysis	K931595
Better Water, (615) 355-6063	
Water Treatment System for Hemodialysis	K920186

Intended Use: H2Only Water Purification System for Hemodialysis is intended for use in hemodialysis treatment. It is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. When used as a medical device, Federal law restricts this device to sale by or on the order of a physician.

Device Description

The H2Only Water Purification System for Hemodialysis is a complete water purification system and consists of either one (1) or two (2) reverse osmosis units (RO). Our recommendation to use an RO individually is based upon feed water quality and the demand of water to be used. Pretreatment includes activated carbon filtration media to remove organics, namely chlorine and chloramines. In order to optimize the performance of the RO system, the following items, are utilized:

1) a water break tank or back flow preventer as required;

2) booster pumps as required to increase the feed pressure to the treatment equipment;
3) a water softener to remove scale-forming minerals;
4) cartridge filters to remove suspended solids;
5) a temperature blending valve to produce the desired water temperature.
   In order to compensate for fluctuations in demand, an air-tight storage tank with a 0.2 micron vent filter, level control and internal spray array is utilized to store RO product water until needed. The first RO system feeds the storage tank, the second RO system is fed from the storage tank and its product water is directly fed to the distribution plumbing. What ever water is not used in the distribution loop is returned to the storage tank, thus a constant recirculation flow is maintained in the distribution plumbing loop.
6) when only one RO system is utilized, Ultraviolet disinfection, Deionization Exchange Tanks and Ultrafilters are also incorporated into the system design.

By utilizing this twin RO system concept a few components can be eliminated from the system design. These components are: Deionization backup tanks, ultraviolet sanitizer, ultrafilters and repressurization pumps. The elimination of these additional components improves system reliability and reduces overall system operational costs . Also by using the twin RO design the system may be safely operated on either RO system feeding the distribution loop, this feature provides system backup and eliminates down time.

When feed water quality demands or when requested by the facility physician, optional devices can include the following components:

1) cartridge filtration for the removal of silt or feed water sediment;
2) automatic backwashing multimedia filter for the removal of suspended solids;
3) ultraviolet disinfection to reduce bacteria either in the influent water supply or on the product supply;
4) a booster pump to increase influent water pressure sufficient to provide adequate flow and pressure to the water treatment system.

Water treatment components are recommended based on the demand of water required, a feed water analysis, and the ability to produce water which meets AAMI standards. H2Only Water Systems will always recommend a water purification system which will exceed Hemodialysis Water Quality Standards as set forth by AAMI.

Summary of Technological Characteristics

H2Only Water Purification Systems designs, recommends and assembles the components of the system. H2Only Water Systems is not the manufacturer of several of the components and is not the manufacturer of component parts which are assembled by H2Only Water Systems.

Although, H2Only Water Purification Systems recommends the water treatment system and components, the dialysis facility's physician has ultimate authority of the type of equipment installed for water purification. The recommended system consists of the following components. A complete system and the intended purposes of each components are described below. Our design is of equivalent to that of the predicate devices.

Hot and cold filtered water supplies are mixed together using a **temperature blending valve** to the desired 77 degrees. Sufficient water pressure must be supplied in order to operate the water treatment equipment effectively. If sufficient pressure is not available, a **booster pump** is installed to supply the required flow and pressure of feed water. If silt or fine sediment are present in the feed water supply, **optional filtration** is used, 5.0 micron filter cartridges can be used to remove the fine sediment and silt. Next, the water flows through dual exchange **carbon filters** to remove the chlorine, chloramines and other organics from the water supply. The carbon filters are sized to provide adequate empty bed contact time of 3-5 minutes for chlorine and 6-10 minutes for chloramines. Water is then directed to **the water softener** where calcium and magnesium ions are exchanged for non-scaling sodium ions. Water is next directed to a **multi cartridge 5.0 micron filter** housing where sediment is removed.

The "pre-treated" water then enters into the **reverse osmosis** membrane where dissolved minerals are rejected from the product stream. The product or permeate water is where dissolved minerals are rejected from this water stream. The product water, permeate, then enters Into a **storage tank.** The storage tank is complete with a sub micron vent filter to prevent airborne bacteria from entering into the storage tank. Stored product water is then used to feed the second RO system and its product water is directly fed to the distribution plumbing. What ever water is not used in the distribution loop is returned to the storage tank, thus a constant recirculation flow is maintained in the distribution plumbing loop.

Identification of Components

Temperature Blending Valve - is used to blend hot and cold water to achieve a temperature of 77 degrees. Tempered water increases the efficiency of the reverse osmosis unit.

Break tank with air gap or back flow preventer is used to prevent a water back flow condition from occurring. Either one meets local plumbing codes.

Booster Pump - (optional) is used to increase the influent water pressure. The reverse osmosis unit, as well as the other pretreatment equipment, requires sufficient feed water pressure to operate.

Multi-media Filter - (optional) is used to remove suspended solids from the feed water supply. Excessive suspended solids can cause malfunction of pretreatment components, i.e. media plugging, moving parts binding etc.

Water Softener - is used to remove calcium and magnesium bicarbonate from the influent water supply. Calcium and magnesium bicarbonate will cause the reverse osmosis membrane to scale, thus reducing production of treated water.

Backwashing Carbon Filters - are used to remove organics, namely chlorine and chloramines, from the influent water supply. Chlorine will attack and destroy the reverse osmosis membrane, thus reducing the quality of the treated water. Also, AAMI recommends that chlorine and chloramines be removed from the treated water supply.
By occasional backwashing of the carbon beds, the carbon media is not allowed to become compacted in the tank and the possibility of channeling is greatly reduced. If a carbon bed channels, the effectiveness of the media is greatly reduced.

Reverse Osmosis Unit #1 - rejects inorganics, dissolved minerals, suspended solids and microbiological contaminants from the product water stream. In order to meet AAMI standards for dissolved inorganics, a reverse osmosis unit is utilized.

Storage Tank - stores reverse osmosis product water and acts as a integral part of the dialysis water loop. The storage tank utilized in this design is a cone bottom on a stand to insure complete drainage when sanitizing. The reverse osmosis unit produces water at a steady rate which is sometimes slower than demand, the storage tank will allow for fluctuations in this demand. The storage tank is equipped with level sensors to turn on the reverse osmosis unit when water is required, and to turn off when the tank is full. A vent filter removes airborne bacteria while allowing the tank to breathe. A spray array is utilized in the sanitization mode so that the interior of the tank is continually rinsed.

Reverse Osmosis Unit #2 - Stored product water is then used to feed the second RO system and its product water is directly fed to the distribution plumbing. What ever water is not used in the distribution loop is returned to the storage tank, thus a constant recirculation flow is maintained in the distribution plumbing loop. The water produced meets or exceeds AAMI standards for dissolved inorganics.

Remote Audible / Visual Alarm - is mounted at the nurses station and activates when an alarm / alert condition occurs in the RO system located in the water treatment room. The RO system may be shut down from this location, but must be restarted from the RO controller.

Deionizer Exchange Tanks - are sometimes incorporated into the system design as a water polish and back up to the single RO system. DI is used to remove inorganic water contaminants and dissolved gases from the water supply. By using water quality monitoring devices, this method assures treated water will meet AAMI recommended standards for inorganic removal. Whenever deionization exchange tanks are used in a water purification system for hemodialysis, sub micron membrane post filtration is used to remove any suspended solids and bacteria. Also, a temperature-compensated quality-indicating device is installed on all systems utilizing deionization exchange tanks. For additional safety, a remote audible/visual alarm is installed at the nurses' station to indicate any problems that may occur in the water treatment room.

Ultraviolet (UV) Disinfection Units are normally installed when Deionization exchange tanks are utilized in the system. Ultraviolet is a safe, clean and effective means to rid the water of bacteria, mold, virus and algae with out the use of heat or chemicals. A UV intensity monitor is also used any time a UV disinfection unit is installed in a water system.

Ultra Filters & Sub micron Post Filters - are used to remove any suspended solids, "free floating" bacteria, and inhibit pyrogens from entering the water used in dialysis. Post filters must be used in conjunction with storage tanks, DI and UV.

Monitoring Devices - are used to assure the proper performance of the water treatment equipment. Pressure gauges, flow meters, temperature-compensated water quality monitors, test ports, temperature gauge, water meter, etc. are installed at specific points throughout the system to measure each component's performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Mr. Richard C. Herzberger
H2Only Company
Serve-A-Pure Company
1101 Columbus Avenue
Bay City, MI 48708

Re: K993520
H2Only Complete Water Purification
System for Hemodialysis
Dated: February 11, 2000
Received: February 14, 2000
Regulatory Class: II
21 CFR §876.5665/Procode: 78 FIP

Dear Mr. Herzberger:

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): K993520

Device Name: H2Only Complete Water Purification System for Hemodialysis

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Carolyn Y Neuland for DBS
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993520