Section 5
Summary of Safety & Effectiveness

Dayton Water Systems' UltraPure Water Treatment System
for Hemodialysis

submitted by
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Contact: Cindy Helton
February 2, 1998
updated: December 29, 1998

Common or Classification Name: Water Purification System for Hemodialysis

Proprietary Name: Dayton Water Systems' UltraPure Water Treatment System for Hemodialysis

Claiming substantial equivalence to:

Better Water Inc.
Water Treatment System for Hemodialysis
(K920186)

Intended Use: Dayton Water Systems' UltraPure Water Treatment 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.

K981680
p. 2/7

Device Description

The Dayton Water Systems' UltraPure Water Treatment System for Hemodialysis is a complete water purification system and consists of a reverse osmosis unit (RO) and/or deionizer exchange tanks (DI) to demineralize the water. Our recommendation to use RO and DI in conjunction or 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 softener to remove scale-forming minerals; 2) cartridge filters to remove suspended solids; 3) a temperature blending valve to produce the desired water temperature. In order to compensate for fluctuations in demand, an air-tight storage tank with vent filter, level control, and internal spray array is utilized to store RO product water until needed. Repressurization pumps are employed to provide adequate flow and pressure to points of use.

Whenever a storage tank or deionizer exchange tanks are used in a water purification system for hemodialysis, submicron 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 deionizer 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.

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) automatic backwashing carbon dioxide reduction filter (calcite filter) for the reduction/removal of CO_2; 4) ultraviolet disinfection to reduce bacteria either in the influent water supply or on the product supply; 5) iodinator for the introduction of an iodine residual to the storage tank to inhibit bacteria growth (NOTE: DI tanks must be used to remove the residual iodine from the product water before use in hemodialysis treatment); and 6) a booster pump to increase influent water pressure sufficient to provide adequate flow and pressure to the water treatment system.

K981680
p.3/7

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. Dayton Water Systems will always recommend a water purification system which will exceed Hemodialysis Water Quality Standards as set forth by AAMI (Fig. 5-1).

Summary of Technological Characteristics

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

Although, Dayton Water Systems recommends the water treatment system and components, the dialysis facility's physician has ultimate authority of the equipment installed for water purification. The recommended system (Fig. 5-2) 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 device.

Hot and cold filtered water supplies are mixed together using a **temperature blending valve** to the desired 77°F. 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, fine sediment, or low pH conditions are present in the feed water supply, **optional filtration** is used. A calcite filter can be used to neutralize low pH due to high levels of dissolved carbon dioxide. A .35 micron filter cartridge can be used to remove the fine sediment and silt. Water is then directed to **the water softener** where calcium and magnesium ions are exchanged for non-scaling sodium ions. 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.

K981680
p. 4/7

The "pre-treated" water then enters into the **reverse osmosis** membrane where dissolved minerals are rejected from the product stream. The product water, permeate, enters into a **storage tank**. The storage tank is complete with a submicron vent filter to prevent airborne bacteria from entering into the storage tank. An **iodinator** can be installed as an option on the return water line to the storage tank to add a residual of iodine to inhibit bacteria growth. Stored product water is then repressurized by **the repressurization pump** for distribution through the dialysis loop. After the repressurization pump and before the dialysis loop, **mixed-bed deionizer exchange tanks** are installed to remove dissolved minerals and dissolved gases from the water to be used to dilute dialysate. In rare circumstances when requested by the physician in charge of the facility, an **ultraviolet disinfection** unit is used to kill bacteria. **Submicron membrane post filters** are used to remove bacteria and pyrogens from entering into the dialysis loop. Submicron membrane post filters must be used in conjunction with storage tanks, UV and DI. Fibercore ultrafilters are used as post filtration. However, the WET filter may be used as a primary filter to the Fibercore ultrafilter to remove larger particles down to .2 micron.

Identification of Components

5 Micron Prefilters (Hot and Cold) - are used to filter particulate and suspended solids from the incoming water supply. Any suspended solids in the water supply could cause a malfunction of any of the water treatment components.

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

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.

Calcite Filter - (optional) is used to neutralize the pH of the influent water source due to dissolved carbon dioxide in the water supply. Excessive CO_2 in the influent water supply will adversely effect the pH of the product water of the reverse osmosis unit. CO_2 will also accelerate the exhaustion of the deionizer exchange tanks.

K981680
p 5/7

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.

.35 Micron Filter - (optional) is used to remove very small particulate and suspended solids, such as silt, that are not removed by the 5 micron prefilters. Suspended solids will cause the reverse osmosis membrane to "plug up", thus reducing production of treated water.

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.

Exchange 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.

Reverse Osmosis Unit - 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 reverse osmosis unit produces water at a steady rate which is sometimes slower than demand. The storage tank will allow for fluctuations in 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 so that the interior of the tank is continually rinsed.

Repressurization/Recirculation Pump - serves two purposes. First, it is used to repressurize the water in the storage tank and delivers the water to the dialysis loop and the machines. Second, it is used to continuously recirculate the water in the dialysis loop piping at the recommended velocity of 5 feet per second, to inhibit bacteria growth.

K981680
p. 617

Central Control Panel - acts as the integral central processing unit which monitors the level of the water the storage tank, includes the quality monitor for the DI tanks, and controls the production of RO permeate. The central control panel also controls the operation of the repressurization/recirculation pump. The central control panel interacts with the remote audible/visual alarm to alarm at the nurses' station when one of the following alarm conditions arise: 1) low water level in the holding tank; 2) low quality water in the product loop; 3) RO malfunction; 4) low feed water pressure; and 5) other alarm/alert levels as desired by the facility.

Remote Audible/Visual Alarm - is mounted at the nurses station and activates when an alarm/alert condition occurs in the water treatment room.

Deionizer Exchange Tanks - are used to remove inorganic water contaminants and dissolved gases from the water supply. Using water quality monitoring devices, this method assures treated water will meet AAMI recommended standards for inorganic removal. When utilizing deionizer exchange tanks, submicron membrane filtration must be used.

Ultraviolet Disinfection Unit - is used to kill bacteria at up to 99.9% efficiency utilizing 254 nm ultraviolet waves. Ultrafiltration or submicron membrane filtration is recommended to inhibit endotoxins from entering into the process stream.

Ultra Filters & Submicron 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.

Iodinator - is used to add a residual of iodine to the holding tank. The iodinator is installed as a split-stream so that water returning from the loop to the holding tank has a residual of iodine. The iodine residual inhibits bacteria growth in the storage tank where water flow velocity is not 5 feet per second. The iodine is removed from the treated water by the deionizer exchange tanks before distribution to the loop. An iodinator can be utilized *only* when deionizer exchange tanks are used.

K981680
p.717

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.

Performance Data

Results of clinical testing were performed on a water purification system and are attached as Fig. 5-3. This test sample was pulled from the test port which is on the return to the storage tank approximately 48 hours after start-up. This testing indicates that after 48 hours water in the dialysis loop still meets the AAMI standards. Thus, as with the predicate device, this water purification system successfully meets performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 31 1998

Ms. Cindy Helton
Quality Assurance Manager
Dayton Water Systems
430 Leo Street
Dayton, OH 45404

Re: K981680
Ultrapure Water Treatment System for Hemodialysis
Dated: November 5, 1998
Received: November 6, 1998
Regulatory Class: II
21CFR 876.5665/Procode: 78 FIP

Dear Ms. Helton:

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

Section 1
Device Name

The classification device name of this system is Water Purification System for Hemodialysis. The proprietary device name is Dayton Water Systems' UltraPure Water Treatment System for Hemodialysis.

Statement of Intended Use

Dayton Water Systems' UltraPure Water Treatment 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.

Prescription

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981680/S'