K041884
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FEB 2 8 2005

Mueller
WATER CONDITIONING, INC.
1500 Sherwood Forest Dr. • Houston, Texas 77043
(713) 467-3226 • Fax (713) 467-9018

510(k) Summary

Mueller Water Conditioning, Inc.
1500 Sherwood Forest Dr.
Houston TX 77043

Phone: 713/467-3226
Fax: 713/467-9018

Contact:	David W. Mueller
Date of summary preparation:	June 1, 2004
Device Name:	
Proprietary Name:	Mueller RO/DI System for Hemodialysis
Common Name:	Water Purification System for Hemodialysis
Classification:	
Class II CFR #876.5665 Product Code: F1P	
Device claiming equivalence to:	U.S. Filter Corporation Water Purification System for Hemodialysis 510(k) #K980182

DEVICE DESCRIPTION

The Mueller RO/DI system for hemodialysis treats incoming facility water to provide water conforming to AAMI standards for hemodialysis use in respect to organic and inorganic substances as well as microbial contaminants for water intended for use as dilute dialysate, bicarbonate, acetate and sterilant for dialyzer reprocessing.

The core components of the system include carbon filters along with reverse osmosis (RO) unit and portable exchange deionization tanks along with appropriate alarms to remove oxidants from the water that are harmful to patient health. 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 will include multi-media filtration, water softening, carbon filtration, and sediment filtration.

Post treatment is used after the RO unit to polish and monitor the water going to the hemodialysis machines. It typically includes repressurizing/recirculation pumps, flow meters, Deionization tanks, conductivity/resistivity monitor, U.V. sterilization and sub-micron filtration.

The Mueller Water Conditioning, Inc. (MWCI) water purification system utilizes no new water purification techniques. Carbon filtration, water softening, multimedia filtration, cartridge filtration, reverse osmosis (R.O.), deionization, ultraviolet light and particulate filtration are the core methods of treatment for this system. The storage, piping, repressurization, emergency bypasses, sanitization, labeling, training and documentation round out the efforts to ensure proper delivery of the treated water. The registered device we are claiming substantial equivalent to uses virtually the same basic principles to perform their function.

Below is a summary for each component of the system.

Multimedia Filters

MWCI uses multimedia filters constructed of materials that are F.D.A. or "NSF" approved. Dependant upon system requirements and/or physician direction, either time clock or meter-initiated filters may be used, either in a single, twin or twin alternating configuration. Where time clock or metered single filters are used, an interlock relay precludes R.O operation during filter backwash operations.

Water Softeners

MWCI uses water softeners constructed of materials that are F.D.A. or "NSF" approved. Dependant upon system requirements and physician direction, either time clock or meter-initiated softeners may be used, either in a single, twin or twin alternating configuration. Where time clock or metered single softeners are used, an interlock relay precludes R.O. operation during softener regeneration.

Carbon Filtration

Chloramines and chlorine are both filtered utilizing carbon filtration in a "worker-polisher" configuration with test ports immediately after each filter. Minimum empty bed contact time (EBCT) of 6-10 minutes is incorporated into MWCI system designs as recommended by the FDA. MWCI recommends testing for chlorine and chloramine breakthrough prior to each patient shift. Bypass piping of the carbon filtration is not allowed in either system. Both utilize carbon with a minimum 900 iodine number. In instances where single-patient systems are in use, MWCI allows for the use of single-tank carbon filtration where minimum standards EBCT can be met, but in no instances is a multi-patient system installed without worker-polisher carbon tank configuration unless so directed by the attending physician.

Cartridge Filtration

MWCI uses R.O. particulate cartridge filtration of non-cotton construction. Where an R.O. cannot be shut down for cartridge replacement, dual filter housings are installed with isolation valves to allow for individual cartridge replacement while the R.O. is in operation. MWCI uses 1 or 5 micron cartridge filtration of melt-blown construction.

Reverse Osmosis

MWCI uses only R.O. units that are registered Medical devices. Modification to the R.O. system as delivered by the manufacturer is forbidden unless properly authorized by the manufacturer and documented. R.O. systems utilized by MWCI must have connections for external, remote alarms for installation into the dialysis treatment area (typically in the nurses' station). Use of the remote alarms allows for monitoring of the system performance without having to be in direct view of the system.

Water Storage

MWCI uses R.O. water storage tanks constructed of F.D.A. or "NSF" approved materials (fiberglass, polypropylene or polyethylene) with filtered vents. Vent filters are replaced annually.

Repressurization/Recirculation

MWCI uses R.O. product water repressurization/recirculation pumps sized for adequate flow and pressure for the intended use. Where possible, the pump is sized for a nominal flow velocity of 3 feet per second (fps) velocity at the lowest system flow point. Where Direct Feed systems may be used, nominal flow velocity shall be 1.5 fps at the point where the loop return feeds to the R.O. inlet. Where dual recirculation pumps are installed, the pumps shall be installed in a parallel configuration and alternated weekly to minimize water stagnation. This pump alternation shall be accomplished either manually or automatically depending on the direction of the attending physician.

Piping

MWCI uses PVC schedule 80 piping and valves for water distribution post-R.O., unless otherwise directed by the attending physician. Pre-R.O. piping may include a combination of galvanized, copper, brass and PVC piping and valving.

Deionization

Unless otherwise directed by the attending physician, MWCI uses mixed-bed deionization tanks in a series, "worker-polisher" configuration. MWCI uses a local 1-megohm quality control light on the "worker" tank, and a temperature compensated resistivity monitor on the "polisher" tank. The resistivity monitor receives annual calibration utilizing NIST traceable calibration equipment as directed by the monitor manufacturer unless otherwise directed by the attending physician. The monitor has a remote alarm capability or is itself installed in the common area (such as the nurses' station) of the unit, with the probe installed immediately after the polishing deionizer. The alarm set point of the resistivity monitor is set to indicate an alarm condition at 5 megohms, unless otherwise directed by the attending physician.

Final Filtration and U.V. Lamps

MWCI uses 0.2-micron absolute final filters and/or ultrafiltration in all system designs to remove bacterial contamination and control endotoxin levels. MWCI also uses UV lamps in all system designs unless otherwise directed by the attending physician, with the final filters installed downstream of the UV lamps.

Emergency bypass

MWCI provides emergency bypass lines and valving that are clearly tagged and labeled. Usage instructions and staff in-service training will be provided by MWCI to the end user and/or their agents as identified by the customer.

SANITIZATION

To avoid additional valving and/or dead legs, introduction of sanitizing agents shall be via either the storage tank or the deionization tank connections unless otherwise directed by the attending physician.

In summary, the MWCI system is quite similar in design and function to other systems already in the marketplace. The basic water purification components and methods are identical. Most of the differences in design and function are based on the efforts of MWCI to provide reliable, cost-effective treatment and design.

INTENDED USE STATEMENT

Mueller Water Conditioning's 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.

TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

COMPARISON	MUELLER WATER CONDITIONING	U.S. FILTER
Intended Use:	Hemodialysis Water Treatment	Hemodialysis Water Treatment
Equipment:	Incorporates FDA-certified R.O. unit	Incorporates FDA-certified R.O. unit
Pre-Treatment Equipment:	Designed based upon water analysis, R.O. manufacturer's requirement, and AAMI specs.	Designed based upon water analysis, R.O. manufacturer's requirement, and AAMI specs.
Water Contact Materials:	FDA NSF Compliant	FDA NSF Compliant
Safety Features:	Utilizes R.O. safety features. Water conductivity/resistivity and tank water self-monitored and alarmed.	Utilizes R.O. safety features. Water conductivity/resistivity and tank water self-monitored and alarmed.
Performance:	Meets or exceeds AAMI Standards	Meets or exceed AAMI Standards
Capacity:	Determined by R.O. Capacity	Determined by R.O. Capacity

CONCLUSION OF PERFORMANCE DATA

The following data was obtained from a test system installed at our facility in Houston, TX. The customer has the ultimate responsibility for determining the quality of the water used for dialysis, but the following results show the water tested to AAMI standards.

COMPONENT	RESULT	UNITS	REFERENCE	MEETS OR EXCEEDS AAMI STANDARDS
Sodium Water	0.054	mg/L	70	Yes
Potassium, Water	<1.000	mg/L	0.8	Yes
Aluminum, Water	<0.008	mg/L	0.0.01	Yes
Calcium, Water	<0.050	mg/L	0-2	Yes
Copper, Water	<0.005	mg/L	0-0.1	Yes
Magnesium, Water	<0.050	mg/L	0-4	Yes
Selenium, Water	<0.005	mg/L	0-0.09	Yes
Zinc, Water	<0.005	mg/L	0-0.1	Yes
Chromium, Water	<0.005	mg/L	0-0.014	Yes
Chlorine	0.0	mg/L	0.5	Yes
Chloramine	0.0	mg/L	0.1	Yes
Lead, Water	<0.002	mg/L	0-0.005	Yes
Arsenic, Water	<0.002	mg/L	0-0.005	Yes
Mercury, Water	<0.0002	mg/L	0-0.0002	Yes
Cadmium, Water	<0.0010	mg/L	0-0.001	Yes
Beryllium, Water	<0.0004	mg/L	0-0.0004	Yes
Antimony, Water	<0.006	mg/L	0-0.006	Yes
Thallium, Water	<0.002	mg/L	0-0.002	Yes
Silver, Water	<0.003	mg/L	0-0.005	Yes
Barium, Water	<0.001	mg/L	0-0.1	Yes
Fluoride, Water	<0.10	mg/L	0-0.20	Yes
Nitrate, Water	<0.2	mg/L	0-2.0	Yes
Sulfate, Water	<1.0	mg/L	0.100	Yes
pH	5.7	UNITS		
Resistivity	0.769			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2005

Mr. David W. Mueller
Vice President
Mueller Water Conditioning, Inc.
1500 Sherwood Forest Drive
HOUSTON TX 77043

Re: K041884
Trade/Device Name: Mueller RO/DI System for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: January 31, 2005
Received: February 1, 2005

Dear Mr. Mueller:

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 (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 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); 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.

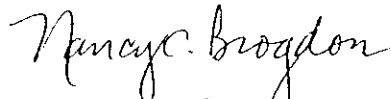
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Mueller
WATER CONDITIONING, INC.

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Tel: 713-467-3226
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Indications for Use

510(k) Number (if known): K041884

Device Name: Mueller RO/DI System for Hemodialysis

Indications for Use:

Mueller Water Conditioning's Water Purification System for Hemodialysis is intended for use in hemodialysis treatment. The system is used to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate and to produce purified water for dialyzer reprocessing, equipment rinse and disinfection. When used as a medical device, Federal law restricts this device to sale by or on the order of a physician.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Ayres

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041884