

JAN 14 2000

K991916
P1/3

SECTION 8

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by: VIRGINIA WATER SYSTEMS, INC.
7433 Whitepine Road
Richmond, VA 23237
(804) 743-0034

Contact: William G. Garrahan

Dated: May 25, 1999

Classification Name: Water Purification System for
Hemodialysis

Proprietary Name: Virginia Water Systems' Water
Purification for Hemodialysis

Claiming Substantial
Equivalence To:

Osmonics Osmo 23G Series Reverse
Osmosis / K931595B

MarCor Complete Water Treatment
System for Kidney Dialysis / K945559

Gambro Central Water Treatment System
CWP100-W / K974899

Dayton Water Systems Ultrapure Water
Treatment System for Hemodialysis
K981680

Device Description:

Virginia Water Systems' Water Purification for Hemodialysis is a complete water treatment system used in the production of ultrapure water used in hemodialysis facilities. The components consist of the following:

Blend Valve - used to temper the incoming water to 77°F.

CHARACTERISTICS

	<u>Design</u>	<u>Material</u>	<u>Chemical Composition</u>	<u>Energy Source</u>
Va. Water	Complete System	Pretreatment RO, Post- treatment	FRP, PVC, SS Polypro	110/220V
Osmonics	RO only	Exact RO unit	Same	110/220V
MarCor	Complete System	Same	Same	110/220V
Gambro	Complete System	Same	Same	110/220V
Dayton	Complete System	Same	Same	110/220V

Statement of Intended Use:

Virginia Water Systems' Water Purification for Hemodialysis is intended to remove organic, inorganic, and microbial contaminants from water used to make dialysate and reprocess dialyzers as well as rinsing and disinfection of the dialysis equipment. When used as a medical device, Federal law restricts this device to sale by or on the order of a physician.

Device Description (cont'd)

Inlet Booster Pump - increases incoming water pressure to the pre-treatment and RO unit.

Multimedia Filter - removes incoming particles to a level of ten (10) microns.

Softener - reduces hardness constituents in incoming water.

Carbon Tanks - two (2) tanks in series that remove chlorine, chloramine, and organics. Ten (10) minutes empty bed time ensures complete chloramine removal.

Reverse Osmosis Unit - removes 95-98% of incoming minerals and 99% of organics. This is the primary treatment in most instances.

Water Storage Tank - retains product water from reverse osmosis unit as well as water recirculated through dialysis loop.

Repressure Pumps - supply pressure of water out of storage tank to the post-treatment equipment and the loop.

Deionizer - removes remaining minerals in RO product water as well as functions as a back-up to the reverse osmosis unit during periods of pre-treatment or RO problems.

Ultraviolet Light - kills bacteria in product water of RO, DI, or from the recirculation loop.

Submicron Filter - removes bacteria and particles greater than .2 micron from the product water and loop.

Hollow Fiber Filter - provides pyrogen removal with .05 micron filtration.

Technological Characteristics - Virginia Water systems claims equivalence in terms of technological characteristics, including design, material, chemical composition, and energy source as the predicate devices. A summary is as follows:



JAN 14 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. William G. Garrahan
Virginia Water Systems, Inc.
7433 Whitepine Road
Richmond, VA 23237Re: K991916
Virginia Water Systems' Water Purification System
for Hemodialysis
Dated: October 13, 1999
Received: October 20, 1999
Regulatory Class: II
21 CFR §876.5665/Procode: 78 FIP

Dear Mr. Garrahan:

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

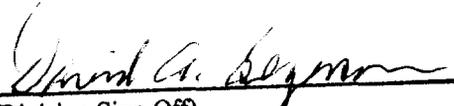
Enclosure

SECTION 7

INDICATION FOR USE STATEMENT

Virginia Water Systems' Water Purification for Hemodialysis is intended to remove organic, inorganic, and microbial contaminants from water used to make dialysate and reprocess dialyzers as well as rinsing and disinfection of the dialysis equipment. When used as a medical device, Federal law restricts this device to sale by or on the order of a physician.

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991916