AUG - 9 2004

510(k) Summary of Safety and Effectiveness

Submitter: Performance Water Systems, LLC
13601 South Kenton Ave.
Crestwood, IL 60445

Establishment Registration Number: 9058752

Phone: (708) 396-0136

Fax: (708) 396-0137

Date Prepared: Oct. 31, 2003

Contact Person: Robert Downey

Device Names:

Trade Name: Performance Water Treatment System

Common Name: Complete Water Treatment System with pre-treatment and product water distribution

Classification Name: Water purification system for Hemodialysis
(21 CFR 876.5665)
Class II Critical Medical Device

Product Code: 78 FIP

Predicate Device: Better Water, Inc. Water Purification System for Hemodialysis, K#920186/C

Device Description:

The water treatment system and its components consisting of; pre-treatment, reverse osmosis machine, and the product water distribution components, are designed to remove microbiological, organic, and inorganic contaminants from the tap water to supply dialysis machines for the preparation of dialysate solutions for hemodialysis treatments.

Pretreatment components can include a tap water boosting system, blending valve, sediment filtration, carbon removal filters, water softeners, and all the necessary interconnecting plumbing. The purpose of this part of the system is to ensure that properly conditioned water is supplied to the reverse osmosis machine to ensure its safe and trouble free operation. The blending valve ensures that the water is at the proper temperature when entering the reverse osmosis machine. The tap water booster system helps ensure that the reverse osmosis machine has adequate water pressure and volume so it can produce the desired amount of water. The sediment filters can be in the form of an automatic backwashing filter (such as a multi-media depth filter), or as a replaceable filter cartridge. The carbon filters are installed primarily to remove the amount of chlorine and chloramines from the water to meet the necessary water quality standards and can be in the form of automatic backwashing tanks, or portable exchange tanks. The water softener(s) are in place to remove the hardness from the tap water to both meet water quality standards, and to protect the reverse osmosis membranes from scaling and therefore not performing to specifications.

After the tap water has been pre-treated, it then enters the R.O. (reverse osmosis), where total dissolved solids are removed to pertinent water quality standards. This is accomplished by utilizing a membrane separation process, whereby the incoming water is separated into a product stream, and a concentrate stream. The molecular weight cut-off determines what and how many contaminants are passed through into the product stream. R.O.s used for this application typically remove 95-99% of all total dissolved solids and bacteria.

The product water distribution part of the system is in place to store, provide additional purification if needed, and deliver the purified water to wherever needed. These components can include such things as a storage tank, deionization tanks, final filters (for bacteria and endotoxins), and delivery pumps and controls. Some systems can also utilize an ultraviolet light for additional sterilization properties.

Intended Use: The Performance Water Treatment System is intended to be used to remove organic and inorganic contaminants from a tap water supply to dilute a dialysate concentrate for hemodialysis treatments, as well as for use for dialyzer reprocessing and dialysis equipment disinfecting and rinsing.

Predicate Device: The Performance Water Treatment System and its components are substantially equivalent to the Better Water, Inc. Water Purification System for Hemodialysis, K#920186/C. Both the predicate device systems and the Performance Water Treatment System utilize reverse osmosis technology as the primary means of purification, and all utilize an R.O. which has 510(k) clearance from the FDA.

Non-Clinical Performance Data:
The Performance Water Treatment System produces product water which is in compliance with the standard issued by the Association for the Advancement of Medical Instrumentation, AAMI RD62-2001.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 2004

Mr. Robert P. Downey
Manager
Performance Water Systems, LLC
13601 South Kenton Avenue
CRESTWOOD IL 60445

Re: K033648
Trade/Device Name: Performance Water Treatment System
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: August 1, 2004
Received: August 3, 2004

Dear Mr. Downey:

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

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

Enclosure

K033648

510(k) Number (if known): ~~Not Yet Assigned~~ K033648

Device Name: Performance Water Treatment System

Indications for Use:

The water treatment system and its components consisting of; pre-treatment, reverse osmosis machine, and the product water distribution components, are designed to remove microbiological, organic, and inorganic contaminants from the tap water to supply dialysis machines for the preparation of dialysate solutions for hemodialysis treatments.

NOTE: Federal Law restricts this device to sale by or on the order of a physician for use as a water treatment device for hemodialysis.

(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)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033648