K994279

p.1/2

DEC 22 2000

510 (k) Summary

Submitter: PURE WATER Solutions, Inc.
14550 East Easter Avenue, Suite 800
Englewood, Colorado 80112
Phone 303/693-7610, Fax 303/693-4479
Contact Name: Dean S. Lewis

Classification Name: Water Purification System for Hemodialysis

Device Name: PURE WATER-CDS (Central Dialysis Solution)

Predicate Device: Mar Cor Services, Inc. #K945559

Description of System: The PURE WATER Solutions' Water Purification System for Hemodialysis is designed to provide water of the required quality to meet AAMI standards for dialysate solutions. The system will remove organic, inorganic and microbial contaminants from the influent water supplied to Hemodialysis clinics. This system comes in various sizes to provide the proper volume of water for each individual clinic. It is easily used and maintained by clinic technicians.

The water treatment phase or pretreatment includes multi-media filtration to reduce suspended solids, water softening to reduce hardness and granular activated carbon filters to remove chlorine and chloramines. If finer filtration is required, cartridges with appropriate housings may be used.

The purifier phase includes reverse osmosis (RO) and or portable-exchange deionization (DI). The primary method will be reverse osmosis using an existing FDA cleared device. DI may be selected for use either independently or in conjunction with RO depending upon the influent water analysis, the available space and the demand required. If DI is selected, then 0.1 micron, absolute, final filters will be installed downstream of the DI and a temperature-compensated, conductivity instrument will be used to monitor the quality.

The circulation phase or post treatment may consist of an RO storage tank with an appropriate 0.2 micron, absolute, vent filter, a stainless steel repressurization pump, ultraviolet sterilization, and 0.05 micron, absolute, final filter.

Auxiliary devices such as booster pumps, temperature blending valves, pressure gauges, sample ports, fittings, piping, level control switches and remote alarms are used as needed throughout the system.

A clean-in-place system consisting of an inert plastic or stainless steel pump and a solution tank is used to clean RO membranes. A paracetic acid disinfection product may be used to chemically disinfect the RO while ozone is used to disinfect the circulation phase.

Safety and Effectiveness: All components used in the system are components with existing safety records. Materials of construction consist of stainless steel, polypropylene, polyethylene, or PVC. Water treatment resins are standard resins used in potable and high purity applications and conform to FDA standards 21 CFR 173.25 and filters are validated for low media migration and with demonstrated microbial retentiveness. All of these materials are inert and do not contribute contaminants to treated water systems. The PURE WATER-CDS system is assembled using existing technologies, an RO unit with existing FDA marketing clearance and personnel with certification to Water Quality Association, Lisle, Illinois, standards of system design, maintenance and treatment.

Conclusion: PURE WATER Solutions, Inc. has designed a water treatment system for Hemodialysis. We believe this system is equivalent to an FDA approved system currently on the market, namely, the predicate device from Mar Cor Service, Inc. 510(k) #K945559. The PURE WATER-CDS uses materials that are safe and effective and methods of design, construction and installation sanctioned by current standards in industry. We therefore request that PURE WATER Solutions' PURE WATER-CDS be granted substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2000

Mr. Dean S. Lewis
President
Pure Water Solutions, Inc.
14550 East Easter Avenue
Suite 800
ENGLEWOOD CO 80112

Re: K994279
Pure Water – CDS (Central Dialysis Solution)
Dated: October 1, 2000
Received: October 6, 2000
Regulatory Class: II
21 CFR §876.5665/Procode: 78 FIP

Dear Mr. Lewis:

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) 594-4639. 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
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number K994279

Device Name PURE WATER-CDS

Indications For Use:

This device is intended to remove organic and inorganic substances and microbial contaminants ~~from~~ water that is used to dilute dialysis concentrate to form dialysate, and to produce purified water for dialyzer reprocessing and equipment rinse and disinfection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Bergman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994279

(Optional Format 3-10-98)

✓

Prescription Use
(Per 21 CFR 801.109)