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510(K) SUMMARY

510(K) Number: K121022

SEP 17 2012

Submitter: AmeriWater

Contact: Brian R. Bowman, Quality & Regulatory Administrator
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Proprietary Name: AmeriWater Alarm Panel

Common Name: Alarm Panel

Classification Name: Water purification system for hemodialysis

Classification: Class II Medical Device under §876.5665
Panel: Gastroenterology
Product Code: FIP

Equivalent Device: K991519, AmeriWater Water Purification System

Device Description: The AmeriWater Alarm Panel is designed to let technicians and nurses know when something is not functioning properly with the water equipment. The Alarm Panels warn the user by illuminating an alarm light and sounding an audible alarm, indicating that some limit has been exceeded. This submission is for a design change to the existing AmeriWater Alarm Panel cleared for market use in the AmeriWater Water Purification System (WPS) for hemodialysis applications (K991519). The AmeriWater Alarm Panel design has been upgraded from a panel with switches operating relays, to a digital panel operated by a microprocessor. All of the Alarm Panels are provided with an LCD display that will indicate the status of the water system. The nurse's station remote will correspond to what is indicated on the alarm panel. The selection of possible water properties to be monitored has been chosen during the original purchase of this equipment. The properties that this system can monitor include Low Resistivity, High Conductivity, R/O Alarm, Low Storage Tank, and Low Bicarb. There are also 5 additional dry contact inputs provided

The Low Resistivity alarm warns the user that the measured water resistivity after the DI tanks is outside of the AAMI standards (1 megohm). The Alarm Panel has two 24VAC outputs that can be used to power solenoid valves to divert the water flow to the drain when the resistivity is below the set-point.

The High Conductivity alarm warns the user that the measured water conductivity is higher than the limit that has been pre-determined by the Facility Director. The Alarm Panel has two 24VAC outputs that can be used to power solenoid valves to divert the water flow to the drain when the conductivity is above the set-point.

The R/O Alarm warns the user that the measured conductivity of the water generated by the RO is higher than what has been determined to be appropriate by the Facility Director, and has been programmed into the RO controller.
The Low Storage Tank alarm warns the user that the low water float switch has been activated in the storage tank, and that the RO is not producing water flow sufficient to stay above this low water level.

The Low Bicarb Level alarm indicates when the Bicarb Distribution tank is low and may need to be re-filled if use is to continue.

The 5 additional dry contact inputs are labeled IN4 – 8. When one of these receives a closure from the external source, the LCD will indicate an alarm and display the appropriate AUX #. IN4 = AUX1, IN5 = AUX2, IN6 = AUX3, IN7 = AUX4 & IN8 = AUX5.

An Alarm Silence function is also provided. The Nurse's Station Remote has a set of lights and audible alarm that will indicate with the main panel in the water room. There is no "Alarm Silence" on the Remote Panel. To silence alarm, it will require the user's attention, in the water room. Using the "ALARM SILENCE" button on the main monitoring panel will "silence" the alarm for 3 minutes only. The alarm will re-indicate 3 minutes after each time it is silenced until the condition causing the alarm has been rectified. In the event that there are multiple alarms active at once, the display on the alarm panel will scroll through the alarms.

Indications for Use: The AmeriWater Alarm Panel is intended for use in hospitals and dialysis clinics as an optional component in the AmeriWater Water Purification System (WPS) for hemodialysis applications. The AmeriWater Alarm Panel is intended to notify the operator of conditions that exist with the Water Purification System requiring the operator's attention. The AmeriWater WPS is intended to remove organic and inorganic substances and microbial contaminants from water. The Purified (or treated) water will then be used to prepare and dilute dialysate concentrate to form dialysate and/or rinse dialyzers for multiple use and/or to prepare dilute solutions for reprocessing procedures in multiple-use dialyzers. The Alarm Panels are designed to meet current AAMI and Federal (U.S.) standards.

Model 00850250 –Base Model & Remote. This model includes R/O Alarm, Low Storage Tank, and Low Bicarb. There are also 5 additional dry contact inputs. When one of these receives a closure from the external source, such as a low tank level in a chemical feed system, the LCD will indicate an alarm and display the input number in the alarm display. The alarm panel also includes an Alarm Silence function.

The Remote is installed at the Nurse's Station on the treatment floor. It has a set of lights and audible alarm that corresponds to what is indicated on the main panel in the water room however there is no "Alarm Silence" available on the Remote Panel. To silence the alarm, it will require the user's attention in the water room.

Model 00850251 – Base Model & Remote with Conductivity. This model includes all of the features of the base model with the addition of a conductivity sensor and high conductivity alarm. The Alarm Panel can be used to power solenoid valves to divert the water flow to the drain when the conductivity is above the set-point.

Model 00850252 – Base Model & Remote with Resistivity and Dump Valve. This model includes all of the features of the base model with the addition of a resistivity sensor and low resistivity alarm with dump valve. The Alarm Panel can be used to power solenoid valves to divert the water flow to the drain when the resistivity is below the set-point. A solenoid valve (dump valve) is included with this model to divert water to drain during a low resistivity alarm condition.

Model 00850253 – Base Model & Remote with Conductivity, Resistivity and Dump Valve. This model includes all of the features of the base model with the addition of a conductivity sensor, high conductivity alarm, resistivity sensor, and low resistivity alarm with dump valve.

Statement of Substantial Equivalence: The AmeriWater Alarm Panel in this submission is substantially equivalent to the AmeriWater Alarm Panel currently cleared for market with the AmeriWater Water Purification System under K991519. The original Alarm Panel has been modified to go from the existing panel with switches operating relays, to a digital panel controlled by a microprocessor. The following table compares and contrasts the predicate device and the new device. This table along with the documentation included in this submission demonstrates that there are no new issues of safety or effectiveness associated with this design change, and that the new device is substantially equivalent to the predicate device.

K991519 Alarm Panel	K121022 Alarm Panel
Central monitor of the water treatment system.	Central monitor of the water treatment system.
Switches operating relays	Digital operation controlled by microprocessor
Operated on 115V electrical circuit	Operated on 115V electrical circuit
Transforms down to a 24V for the remote alarm	Transforms down to a 24V for the remote alarm
Off the shelf conductivity and resistivity monitors installed in panel	Conductivity and resistivity monitoring integrated into control
Audible and visible alarms	Audible and visible alarms
Interfaces with the remote alarm; also with audio and visual alarms	Interfaces with the remote alarm; also with audio and visual alarms
Silence button only located on the main panel in the water room	Silence button only located on the main panel in the water room
Silence button has a 180 second reset.	Silence button has a 180 second reset.
Visible alarms remain active when audible alarm is silenced.	Visible alarms remain active when audible alarm is silenced.
Good Water Light	Water quality digital display
RO Alarm light w/ audible alarm	Alarm light w/ audible alarm and digital display
Storage Tank Low light w/ audible alarm	Alarm light w/ audible alarm and digital display
Conductivity Alarm light w/ audible alarm	Alarm light w/ audible alarm and digital display
Resistivity Alarm light w/ audible alarm	Alarm light w/ audible alarm and digital display
Bicarb Low light w/ audible alarm	Alarm light w/ audible alarm and digital display
No additional contact inputs	5 additional dry contact inputs
Remote Good Water Light	Remote Good quality light
Remote RO Alarm light w/ audible alarm	Remote Alarm light w/ audible alarm*
Remote Storage Tank Low light w/ audible alarm	Remote Alarm light w/ audible alarm*
Remote Conductivity Alarm light w/ audible alarm	Remote Alarm light w/ audible alarm*
Remote Resistivity Alarm light w/ audible alarm	Remote Alarm light w/ audible alarm*
Remote Bicarb Low light w/ audible alarm	Remote Bicarb Low light w/ audible alarm

Summary of Performance Testing: The objective of the performance testing was to verify and validate the operation of the new design AmeriWater Alarm Panel for use with the AmeriWater Water Purification System (WPS). The test was conducted on alarm panels with all possible features. Performance testing was conducted on initial production units representing the approved final design of the AmeriWater Alarm Panel. Each of the test units was bench tested to verify that all alarm functions operate as intended. Each unit was tested, simulating normal operation to ensure that all functions operate as intended and meet design specifications and AAMI requirements. 24 VAC lights were used to verify operation of 24 VAC outputs. Bench testing was justified based on the fact that the device does not have any unique interactions with other components in the system. There are no factors that will affect operation of the installed device that cannot be tested in bench testing. Furthermore, 100% of distributed product will be subjected to performance testing prior to shipment. Performance testing was successful and all acceptance criteria were met. Software validation has been conducted in accordance with requirements for a software device with a moderate level of concern. Test data indicates that the monitors are accurate when compared to a known standard over the operation ranges expected. Clinical tests were not completed for this device, but nonclinical tests provided sufficient evidence to support the safety and effectiveness of the device. The results of testing demonstrate that the device is as safe, as effective, and performs as safely and effectively as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 17 2012

Mr. Brian Bowman
Quality & Regulatory Administrator
AmeriWater
1303 Stanley Avenue
DAYTON OH 45404

Re: K121022
Trade/Device Name: AmeriWater Alarm Panel
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: September 12, 2012
Received: September 14, 2012

Dear Mr. Bowman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121022

Device Name: AmeriWater Alarm Panel

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Prescription Use__X__ 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121022