# I. 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

**Submitter's Name:** Isopure Corp
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Simpsonville, KY 40067
Telephone: (502) 722-1000
**Contact person:** Kevin C. Gillespie

**Date of Summary:** January 24, 2012

**Device Name:** Isopure Sodium Bicarbonate Mixing and Distribution System

**Device Classification Name**: Dialysis Holding Tank (876.5820, FIN)

**Device Description:** The Isopure Sodium Bicarbonate Mixing and Distribution System is designed to mix sodium bicarbonate powder into a liquid solution based on the recommended mixing procedures from the powder manufacturers. Once the powder is mixed into a liquid solution and verified for content accuracy, the solution is transferred to an independent distribution tank for transfer through a loop to the individual dialysis machines or to fill jugs which then can be transported to the individual dialysis machines when no distribution loop exists.

The Isopure Sodium Bicarbonate Mixing and Distribution System features the patented SOLUBILIZER™, which utilizes a large volume of water spinning in a vortex manner to dissolve dry powder into a liquid solution that is drawn into a mix tank. The solution is mixed with AAMI quality water according to specifications outlined by the manufactures for the bicarbonate powder. Once the solution has been dissolved and mixed, the solution can be transferred from the mixing tank to the storage delivery tank for distribution to the loop or jugs. The tanks and the SOLUBILIZER™ are sealed to reduce microbial contamination. The sealed design also facilitates CO2 recovery and gassing off of $CO_2$ during the mixing procedure.

The entire system is controlled by programmable control logic (PLC), which operates the system. The PLC will control the mixing, the delivery and disinfection of the complete system. The system PLC is operated through an HMI touch screen which displays the critical aspects of the system, including the operational stages, real-time indication of various steps, and alarm conditions.

**Intended Use:** The Isopure Sodium Bicarbonate Mixing and Distribution System is intended to be used in Hemodialysis facilities for the mixing, storage and distribution of Bicarb liquid concentrate to be used in the treatment of Hemodialysis patients.

**Legally Marketed Devices to which Equivalence is Claimed:** Isopure Corp purchased the Pure Water Inc's Bicarb Mixing, Storage and Distribution System from Pure Water Inc. Isopure intends to manufacture and market the device at its Simpsonville KY location. The intended use of the device has not change, nor have the functionality and any of the contacting components.

**Descriptive Summary of Technological Characteristics and Those of Predicate Devices:** The technological characteristics of the device are the same as the original submitted device under 501(k) K993272, Pure Water, Inc.'s Bicarb Mix, Storage and Distribution System cleared on April 10, 2000.

**Summary of Comparisons of Components**

| Pure Water, Inc. K993272 | Isopure Corp K112427 |
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| **Physical and Operational Comparison** | |
| Pure Water system features two separate tank configuration one for mixing the solution and one for storage of the solution. These tanks are not connected together allowing the system to be configured on site. | This was changed to a single system where both tanks are secured on the same skid/platform. This allows the ease of piping the two tanks together and reduces the chance of "dead legs" in the system |
| Mix tank features a one piece molded open-top cone bottom high density polyethylene tank with a welded NDPE stand and hinged bolt-on cover with a mixer mounted on the cover. | Mix tank features a one piece molded closed top cone bottom high density polyethylene tank with a welded NDPE stand. A powder hopper consisting of high density polyethylene mounted between the tanks to hold powder and a inductor replaces the mixer |
| Filling of the mix tank is operator dependent. The operator must fill the mix tank to markings on the side of the tank by turning on a valve then turning off the same valve once the level is achieved. This same process is required once the powder is added. | This was changed to an automated process. The operator can adjust the initial fill and the final fill from a set-up screen, but once set, the system will fill the exact same level every time the mix is selected. The initial fill and the final fill levels are determined by the operator selecting the desired amount of bicarb to be mixed i.e. 1 bag, 2 bags, 3 bags, or 4 bags. A calibrated flow meter will determine the exact amount of water entering the mix tank. |
| Mixing the solution is accomplished by small batch mixer 1750 rpm which is clamped to the side of the mix tank. | This was changed to an inductor located inside the mix tank. The reason for this change is recommendation for mixing by the powder manufacturers as well as AAMI RD52:2004. The powder is drawn into the system and mixed with water at the hopper located on the front of the system. |
| Mix for 30 minutes and check for correct mixture by specific gravity method or conductivity as per your facility requirements. Once mixing is complete, the mixer switch must be turned to the off position. | Mix will occur automatically once all of the powder has been dissolved. The mix cycle has been changed to 10 minutes per the powder manufacturer's recommendations. |
| Connect the mix tank hose HM1 to the storage tank. Operate transfer switch to the "ON" position to pump liquid concentrate from the mix tank to the storage tank. Remove hose HM1 from the storage tank and replace plug for the tank. | This was changed with the two tanks on the same skid. Once the solution is automatically mixed, the system will require the operator to verify that the batch is correctly mixed. Once the operator passes the batch, the system will automatically turn on the mix/transfer pump then rotate AV1 (3-way actuated valve), and AV2 (3-way actuated valve) to transfer the solution from the mix tank to the distribution tank. Once the transfer is complete, the system |

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| | will automatically turn off the mix/transfer pump and rotate AV1 and AV2 back to their original positions. After complete, the system will open the drain valve and rinse down the mix tank, hopper, and associated piping with RO water in preparation to mix a new batch of bicarb. If bicarb solution still exists in the distribution tank, the system will hold the mix solution in the mix tank until the low level float is activated in the distribution tank. Once activated, the system will automatically up to 75 gallons of mixed solution. If 100 gallons (380 liters) is in the mix tank, the system will only transfer over 2/3 of this solution on the first low tank alarm then the remaining solution on the next low tank activation. |
| Centrifugal direct drive transfer pump 25 gpm at 40 psi to transfer the mixed solution from the mix tank to the distribution tank. The pump is constructed of Glass Reinforced Noryl with a stainless steel wear ring and impeller hub. | Centrifugal magnetic drive transfer pump 40 gpm at 21 psi to mix the solution and transfer the solution to the distribution tank. The pump is constructed of Glass Fiber Reinforced Polypropylene. With a Polypropylene magnetic capsule and alumina ceramic spindle. |
| Piping used to supply RO treated water to the mix tank and to transfer the mixed solution from the mix tank to the distribution tank is schedule 80 PVC pipe and fittings. | Piping used to supply RO treated water to the mix tank and to transfer the mixed solution from the mix tank to the distribution tank is schedule 80 PVC pipe and fittings. |
| Two-way ball valve is used to drain the mix tank as well as a container filling valve located on the front of the tank. The two way valve is constructed of schedule 80 PVC with Teflon seats and EPDM "O" rings. | Two-way ball valve is used to drain the mix tank as well as a container filling valve located on the front of the tank. The two way valve is constructed of schedule 80 PVC with Teflon seats and EPDM "O" rings. A 24 VDC actuated ball valve is connected to the valve which will allow automatic actuation of the valve during operation |
| Three way true union ball valves are used to direct the mixed solution from the mix tank to the distribution tank. The valve is schedule 80 PVC with Teflon seats and EPDM "O" rings. | Three way true union ball valves are used to direct the mixed solution from the mix tank to the distribution tank. The valve is schedule 80 PVC with Teflon seats and EPDM "O" rings. |
| Auto lock fittings are used to connect lines from the mix tank to the distribution tank. Auto lock fittings are constructed of food grade Acetal and Nitrite. | The Auto lock fittings and hose have been removed from the system as a potential source of contamination. |
| A conductivity meter has independent high/low set points that control to SPDT relays. The controller features a 1 mV per digit $\pm$ 0.5% $\pm$ 1 mV recorder output interface with a recorder or data logger to make permanent records. Automatic temperature compensation is provided. By a 10K$\Omega$ thermistor built in to the conductivity cell. | The Signet 8860 Dual Channel Conductivity/Resistivity Controller is a two-channel input device equipped with three saleable 4 to 20 mA outputs and four programmable relays. A selector switch activates two open collector outputs in place of two of the relays for extraordinary output versatility. Dual input and advanced control capability, including percent rejection, difference |

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| | and ratio calculations, together with Signet Conductivity Sensors. Conductivity/Resistivity electrodes are designed to provide versatile installation and accurate sensing across a very broad dynamic range. These electrodes are built with a controlled surface finish to ensure accuracy and repeatability. The standard electrode is constructed 316 SS or Titanium, but there are other materials available for maximum chemical compatibility. Reversible threads or sanitary flanges allow for maximum installation versatility. |
| The 27500 Teflon rotary tank cleaning nozzle features a spray head that is rotated by the pressurized flow of the spray solution. The compact nozzle produces effective solid stream sprays and can be operated at pressures of 10 – 50 psi. | The 27500 Teflon rotary tank cleaning nozzle features a spray head that is rotated by the pressurized flow of the spray solution. The compact nozzle produces effective solid stream sprays and can be operated at pressures of 10 – 50 psi. |
| 3/8" Solenoid valve consisting of glass filled polypropylene and a viton is used to administer RO water to the mix tank. | 3/8" Solenoid valve consisting of glass filled polypropylene and a viton is used to administer RO water to the mix tank. This valve is also used to administer RO water to the hopper and used for disinfection. |
| Storage tank is a high density cone bottom tank with a sealed cap. A 0.2 uS vent filter provides filtration of the replacement air in the tank. The distribution tank is mounted to a NDPE tank stand. | Storage tank is a high density cone bottom tank with a sealed cap. A 0.2 uS vent filter provides filtration of the replacement air in the tank. The distribution tank is mounted to a NDPE tank stand |
| Distribution of bicarb solution; verify Loop Pump switch on the Bicarb Controller is in the "ON" position. Automatic operation – ensure that the power switch on AUTOCHEM 1000 is in the "OFF" position and all indicator lamps are extinguished. Verify LOOP PUMP switch on the RELAY CONTROLLER is in the "ON" position | Distribution is automated so when the Distribute button is pushed, the distribution of the bicarb will begin to purge the distribution line with bicarb. The return loop valve will divert the return loop to drain until the conductivity of the return loop solution is <46 mS. |
| Loop pump is a centrifugal, direct connect pump consisting of Glass Reinforced Noryl casing, 316 stainless steel wear ring and impeller hub. The bicarb loop pump is used to move the bicarb liquid concentrate, disinfect solution, and rinse water from the storage tank to the distribution loop, which goes to each dialysis machine. | Loop pump is a centrifugal, magnetic connect pump consisting of Glass Fiber Reinforced Polypropylene casing, With a Polypropylene magnetic capsule and alumina ceramic spindle. The bicarb loop pump is used to move the bicarb liquid concentrate, disinfect solution, and rinse water from the storage tank to the distribution loop, which goes to each dialysis machine. |
| Inline Flow Meter consists of polysulfone body, 316 stainless steel float and viton seals. The flow meter is placed in the bicarb distribution loop to monitor the flow rate of the bicarb liquid concentrate being distributed. | Inline Flow Meter was changed to an electronic pulse flow meter. The Seametrics SPX low flow meter employs jewel bearings to allow for very low minimum flow rates and superior life. The SPX flow meter has a body material of polypropylene. The lens cover is acrylic for visual flow indication. The rotor assembly is Kynar with tungsten carbide |

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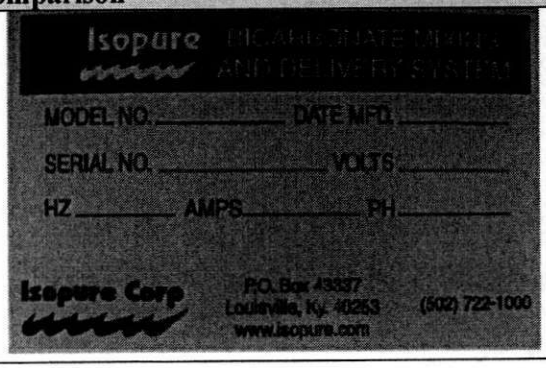
| | shaft (ceramic shaft optional). The O-ring is EPDM.<br>FT420 provides flow rate and total flow indication, with 4-20 mA output capability. |
| UV Light Ideal Horizons SR series UV 316 stainless steel construction ½" FNPT connections. All are constructed using plasma arc or fusion welding, providing strong food grade uncontaminated welds. | UV Trojan UV 316 stainless steel construction ½" FNPT connections. All are constructed using plasma arc or fusion welding, providing strong food grade uncontaminated welds. |
| Submicron Filter a 0.2 micron pleated polypropylene depth filter. Meets FDA requirements for food contact. | Submicron Filter a 0.2 micron pleated polypropylene depth filter. Meets FDA requirements for food contact. |
| 6 Channel Alarm is used to provide warnings from the water and bicarb system. The remote alarm is equipped with indicator lamps and an audio horn. | 6 Channel Alarm is used to provide warnings from the water and bicarb system. The remote alarm is equipped with indicator lamps and an audio horn. |
| Autochem 1000 controller is used to provide mixing control, distribution control and automatic disinfection of the bicarb system. The start switch is guarded to prevent accidental starts. During automatic disinfect process; all switches except the POWER switch are "locked out" to prevent accidental interruption of the process. | The Autochem 1000 was replaced with a Koyo PLC. The Programmable Control Logic (PLC) operates the system utilizing ladder logic. The ladder logic is designed as failsafe logic that in the event of a failure, the system will stop operation. The PLC controls all aspects of the operation including mixing of solution, distribution of the mixed solution, end-of-day process where the sodium bicarbonate is rinsed from the distribution loop, and the disinfection process where the entire system is disinfected. A Human Machine Interface (HMI) touch screen acts as the interface between the operator and the PLC. The HMI provides device operational characteristics such as tank levels, flow rates, solution conductivity, and pressures. The HMI also interfaces the different mix levels in the system. |
| **Labeling Comparison** | |
| Exhibit A Label: Pure Water Concentrate Distribution System Component Name:, Serial No:, Model No:, with name and address of manufacturing facility. |  |

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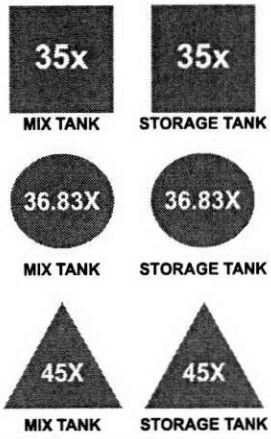
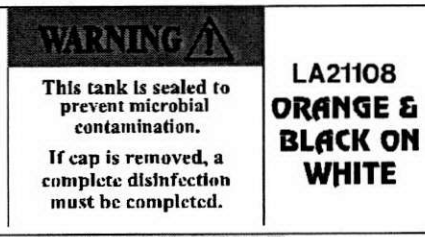
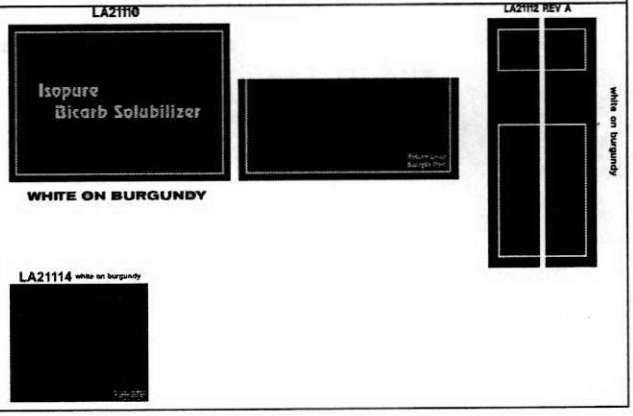
| No Label |  |
| No Label |  |
| No Label |  |
| No Label |  |

**Performance Data:** The basic functionality of the Isopure Sodium Bicarbonate Mixing and Distribution System remains the same as the device cleared on April 10, 2000. The mixing and distribution of the liquid solution still follows the mixing procedures recommended by the powder manufacturers, and all of the contacting materials used in the original cleared device also remain the same. The device physical characteristics did change to reduce the footprint of the device. Operating controls also changed from relays and timers to a PLC (Programmable Logic Control). The changes also address new ANSI/AAMI RD52-2004 requirements to update the mixing system to current regulations.

**Non-Clinical Testing Summary:**
The purpose for the Sodium Bicarbonate Mixing and Distribution System, as for the predicate device, is to provide a bicarbonate solution suitable as part of the dialysate mixture which, along with an acid

solution and RO water, is used to treat dialysis patients. The system has undergone 100% testing to ensure substantial equivalence to the Pure Water, Inc. predicate device. Both systems are fully capable of meeting the mix requirements specified for a suitable sodium bicarbonate solution.

The testing area consists of all components of a water room that would normally be present at a dialysis clinic, including media tanks, a softener, filtering devices, and a reverse osmosis machine. With pure water provided by the RO system and associated components, the Sodium Bicarbonate Mixing and Distribution System was tested repeatedly for proper operation.

The Mix procedure, which performs the operation of mixing the sodium bicarbonate powder into a solution suitable for delivery to a patient dialysis machine, was run for all selectable volumes of bicarbonate. Using the same brand of bicarbonate typically used in an operating clinic, each mix batch was tested for the target conductivity of the solution to confirm the correct mixture, and then transferred to the Distribution Tank. The distribution function was then tested to ensure that circulation of the solution through the loop occurred as expected.
The basic mixing and distribution of sodium bicarbonate in the Isopure system is equivalent to that of Pure Water, Inc.'s original Bicarbonate Mix, Storage and Distribution System cleared April 10, 2000 under Application number K993272. Changes to the mix portion of the system reflect current recommended mixing procedures outlined by the powder manufacturers such as "Vigorous mixing and propeller style mixers can drive carbon dioxide from the solution". "Add water for total volume of mixed solution. Mix again for approx. 10 minutes. Ensure that the powder is dissolved in solution". Changes reflected in this submission to the mixing of the sodium bicarbonate were performed to meet the current requirements of the powder manufacturers, such as the removal of the small batch mixer with a propeller and replacement to a hopper and an inductor located in the mix tank.

**Conclusion:** The information and data provided in this 510(k) Notification establish that the Isopure Sodium Bicarbonate Mixing and Distribution System is as safe and as effective, and performs as well or better than the earlier versions of the Pure Water, Inc. Bicarbonate Mix, Storage and Distribution System cleared April 10, 2000 under Application number K993272.

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

Mr. Kevin Gillespie
President & CEO
Isopure Corporation
141 Citizens Blvd
SIMPSONVILLE KY 40067

JAN 2 6 2012

Re: K112427
Trade/Device Name: Isopure Sodium Bicarbonate Mixing and Distribution System
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIN
Dated: December 21, 2011
Received: December 27, 2011

Dear Mr. Gillespie:

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

# I. INDICATIONS FOR USE STATEMENT

January 24, 2012



**510(k) Number: K112427**

**Device Name:** Isopure Sodium Bicarbonate Mixing and Distribution System

**Indications for Use:**
The Isopure Sodium Bicarbonate Mixing and Distribution System is intended to be used in Hemodialysis facilities for the mixing, storage and distribution of Bicarb liquid concentrate to be used in the treatment of Hemodialysis patients.

(Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112427

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)