MAR 2 9 2012

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.

1. **Submitter's Name:** **Isopure Corp**
   141 Citizens Blvd.
   Simpsonville, KY 40067.
   Telephone: (502) 722-1000
   Contact person: Kevin C. Gillespie
   Date of Summary: December 29, 2011

2. **Device Name:** Isopure ACDS (Acidified Concentrate Distribution and Storage)
   Device Classification Name: Dialysate concentrate for Hemodialysis (liquid or powder) (21 CFR §876.5820, KPO).

3. **Legally Marketed Devices to which Equivalence is Claimed:** Isopure Corp purchased the Pure Water Inc's Acidified Storage and Distribution System with Optional Remote Fill (k993058) from Pure Water Inc. Isopure intends to manufacture and market the device at its Simpsonville KY location. The intended use, functionally of neither the device nor any of the contacting components for the device has changed.

4. **Device Description:** The Isopure ACDS (Acidified Concentrate Distribution and Storage) is designed for storage of pre-mixed acidified concentrate in a 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.

ISOPURE ACDS (Acidified Concentrate Distribution and Storage) with optional remote fill uses "one-piece molded seamless tanks constructed of linear polyethylene" for bulk storage of acidified concentrate.

The optional remote fill allows the storage tanks to be filled by the vendor from outside the building. The Isopure ACDS (Acidified Concentrate Distribution and Storage) with optional remote fill meets or exceeds all Association for the Advancement of Medical Instrumentation (AAMI) National Standards for Hemodialysis.

5. **Indications for use:** The Isopure ACDS (Acidified Concentrate Distribution and Storage) with remote fill is intended to be used in Hemodialysis facilities for the storage and distribution of acid concentrate to be used in the treatment of Hemodialysis patients.

6. **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) K993058, Pure Water, Inc.'s Acidified Storage and Distribution System cleared January 24, 2000.

Summary of Comparisons of Components

Pure Water, Inc K993058	Isopure Corp
The Acidified Tank(s) are designed to store acidified concentrate. The tank(s) are constructed of one piece linear virgin polyethylene. Tanks feature a vented sealed lid to reduce particle contamination. (Pure water acidified storage & distribution 510(k) submission 9/10/99)	The Acidified Tank(s) are designed to store acidified concentrate. The tank(s) are constructed of one piece linear virgin polyethylene. Tanks feature a vented sealed lid to reduce particle contamination.

Acid Fill Controller is a 115 VAC controller that is used to operate the distribution pump when the concentrate is distributed through a loop to the dialysis stations. The controller will also operate the remote filling station by providing power to the receptacle located at the fill station. (Pure water acidified storage & distribution 510(k) submission 9/10/99)	Acid Fill Controller is a 115 VAC controller that is used to operate the distribution pump when the concentrate is distributed through a loop to the dialysis stations. The controller will also operate the remote filling station by providing power to the receptacle located at the fill station.
The filter assembly filters our impurities that may be present in the Acidified concentrate. The filter assembly is comprised of a clear filter housing and a 5 micron 10 inch filter. (Pure water acidified storage & distribution 510(k) submission 9/10/99)	This filter was eliminated because a filter is located on the acidified concentrate mixer for this purpose. Additional filters would serve no purpose and only offers additional opportunities for leakage.
Auxiliary Components A ball valve is placed in the distribution line to fill jugs of concentrate if necessary. (Pure water acidified storage & distribution 510(k) submission 9/10/99)	Auxiliary Components A ball valve is placed in the supply line or the side of the storage tank to fill jugs of concentrate if necessary.
Schedule 80 PVC pipe and fittings: Schedule 80 PVC pipe and fittings are used to direct concentrate flow. (Pure water acidified storage & distribution 510(k) submission 9/10/99)	Schedule 80 PVC pipe and fittings: Schedule 80 PVC pipe and fittings are used to direct concentrate flow.
Polyethylene Flex Tubing: Polyethylene Flex Tubing is used to direct concentrate flow. (Pure water acidified storage & distribution 510(k) submission 9/10/99)	Polyethylene Flex Tubing: Polyethylene Flex Tubing is used to direct concentrate flow.
Autolock Fittings Autolock fittings are used to connect tubing. (Pure water acidified storage & distribution 510(k) submission 9/10/99)	Autolock Fittings Autolock fittings are used to connect tubing.

Performance Data: The Isopure ACDS (Acidified Concentrate Distribution and Storage) is the same device that was manufactured by Pure Water, Inc. under 510(k) 993058. The applicant is notifying the FDA that the device DMR and 510(k) was sold to Isopure who will begin manufacturing the device at its Simpsonville KY location. The only change to the device is the name and manufacturing location. All performance data provided in the original 510(k) remains the same.

7. **Non Clinical Testing:** A validation protocol was performed VP12-002 The following validation test protocol addresses the operation of the ACDS controller, distribution pump, distribution piping, remote fill station, and remote alarm.

ACDS Storage tank:

A 250 gallon storage tank will be assembled with the trim kit to test the operation of all assemblies of the trim kit. This will also test for leaks in the trim kit assemblies and connections to the storage tank. When connected to the tank, the bottom connection should provide acidified concentrate to the distribution pump. The valve will also allow flow to be terminated to the distribution pump when closed.

Level floats: The level floats 2 for the remote fill station the low float will have a dual purpose; 1- for the low tank warning on the remote alarm, and 2- to turn power on for the optional remote fill station. The floats will be tested to ensure proper operation of the remote alarm low level indicator and for the optional remote fill station.

ACDS Control Box: The ACDS control box will be connected to the storage tank and also to the remote fill box to test the operation of the control box. Power will be connected to the control box and the distribution pump will be tested as well as the low level alarm and the optional remote fill station

Distribution Pump: The distribution pump will be connected to a 500 ft ½" polyethylene line to test the distribution of the acidified concentrate through the distribution line. A pressure gauge and a flow meter will also be connected to this line to measure the amount of flow as well as the pressure on the distribution line. The flow meter will be used to verify the operation of the flow switch on the ACDS distribution pump.

Remote Fill Station: A remote fill station will be connected to the storage tank and also to the controller. This will be used to test the on/off electrical connections of the controller in relation to the fill station.

Regulators: In the event that the pressure is excessive (> 5 psig) at the distribution box, a 0-25 regulator is supplied to regulate the pressure at each individual station.

8. Not Applicable to this application

9. Conclusion: Upon instituting the above changes, performance testing was undertaken to verify that the device is as safe, as effective and performs as well as or better than the earlier versions of the Pure Water Inc's Acidified Concentrate Distribution and Storage system (K993058) cleared on January 24, 2000.

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 Corp
141 Citizens Boulevard
SIMPSONVILLE KY 40067

MAR 29 2012

Re: K120005
Trade/Device Name: Isopure ACDS (Acidified Concentrate Distribution and Storage)
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: February 24, 2012
Received: March 1, 2012

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

Indications for Use Statement

December 29, 2011

510(k) Number: K120005

Device Name: Isopure ACDS (Acidified Concentrate Distribution and Storage)

Indications for Use:

The Isopure ACDS with remote fill is intended to be used in Hemodialysis facilities for the storage and distribution of acid 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 K120005

Prescription Use __X___ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)