January 22, 2020

Isopure, Corp.
Kevin Gillespie
President & CEO
11851 Plantside Drive
Louisville, KY 40299

Re: K191093
Trade/Device Name: Isopure Dry Acid Dissolution System
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System And Accessories
Regulatory Class: II
Product Code: KPO
Dated: December 20, 2019
Received: December 23, 2019

Dear Kevin 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

FORM 3881

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191093

Device Name
Isopure Dry Acid Dissolution System

Indications for Use *(Describe)*
The Isopure Corp Dry Acid Dissolution System is designed to mix dry acid concentrates with purified water to produce an acid concentrate solution for hemodialysis for use in 3- Stream (acid concentrate, bicarbonate concentrate, and water) hemodialysis machines.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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.
11851 Plantside Drive
Louisville, KY 40299
(502) 267-7873 x6672

Contact person: Kevin Gillespie

Date of Summary: January 22, 2020

Establishment Registration Number: 3003768032
Device Name: Isopure Dry Acid Dissolution System
Common Name: Hemodialysis System and Accessories
Product Code: KPO
Device Class: II
Classification Name: Hemodialysis System and Accessories
Regulation Number: 21 CFR 876.5820

Predicate Device for Substantial Equivalence: Fresenius Medical Care Dry Acid Dissolution Unit, K131611

Device Description: The Isopure Dry Acid Dissolution System consists mainly of a Mixing Tank, a Distribution and Mixing Pump, a Hopper (with or without an automated opening mechanism), a Venturi inductor, and accompanying hydraulics and control circuits and sensors. The users will enter the dry acid powder mix into the Hopper either manually or by means of the automated bag opening mechanism. The contents of the Hopper will be drawn into the Mixing Tank by means of the Venturi inductor and the Distribution and Mixing Pump. Once all bags have been entered and the solution thoroughly mixed, the reading of the hydrostatic pressure inside the Tank will be converted into a specific gravity value. This in turn will be used to verify that the proper solution has been prepared against a pre-loaded table of values provided by the powder manufacturer. If the solution passes this verification, the system will allow transferring of the solution

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to the corresponding storage tank in the facility. The tanks will be identified by the use of quick connectors with RFID to prevent the transfer hose from being connected to the wrong tank.

Intended Use: The Isopure Dry Acid Dissolution System is designed to mix dry acid concentrates with purified water to produce an acid concentrate solution for hemodialysis for use in 3- Stream (acid concentrate, bicarbonate concentrate, and water) hemodialysis machines.

Substantial Equivalence to Predicate Device:

Technological Comparison to Predicate Device Specifications	**Isopure Dry Acid Dissolution System**	**FMC Granuflo (Dry Acid Dissolution System)**
Classification Name And Product Code		(K131611)
Intended Use	The Isopure Dry Acid Dissolution System is designed to mix dry acid concentrates with purified water to produce an acid concentrate solution for hemodialysis for use in 3-Stream (acid concentrate, bicarbonate concentrate, and water) hemodialysis machines.	The Fresenius Medical Care Dry Acid Dissolution Unit mixes Fresenius Medical Care-distributed dry acid concentrate products with hemodialysis quality water. The resulting liquid acid concentrates are intended for use in three-stream hemodialysis machines calibrated for acid and bicarbonate concentrates.
Water Requirements: *Water Quality*	AAMI Quality (RD 62) / ISO 23500-3: 2019	AAMI Quality (RD 62)
Standards	ISO 23500 (-1, -4): 2019 (NOTE: ISO 23500- 4 replaces ISO 13958: 2014) EN 61326-1:2013 & IEC60601-1-2:2014 (4th Edition)- Emissions (EN55011:2009+A1:2010, IEC 61000-3-2:2014, IEC 61000-3-3:2013)	ISO 23500: 2014 ISO 13958: 2014 EN 61326-1:2013 & IEC60601-1 Emissions IEC60601-1 Immunity

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Technological Comparison to Predicate Device Specifications	Isopure Dry Acid Dissolution System	FMC Granuflo (Dry Acid Dissolution System)
	EN 61326-1:2013 & IEC60601-1-2:2014 (4th Edition)- Immunity (IEC 6100-4-2:2008, IEC 61000-4-3:2010, IEC61000-4-4:2010, IEC 61000-4-4:2012, IEC 61000-4-5:2014, IEC 61000-4-6:2013, IEC61000-4-8:2009, IEC 61000-4-11:2010)	
Batch size	99 gallons and 132 gallons	99 gallons and 132 gallons
Disinfection	Peracetic Acid (45 minutes)	Bleach (30 minutes)
Mix Preparation Method	• Initial Fill • Bag Opening • Concurrent Mix • Final Fill • Recirculation and Mix • QA • Transfer	• Initial Fill • Add Granules • Mix / De-aeration • Final Fill • Homogenize • QA • Transfer
Data Entry	Scan or manual entry of barcode information of boxes and bags into the system	Manual record keeping of information of boxes and bags.
Mixing method	High Flow Recirculation	High Flow recirculation / Mechanical propeller mixer
Powder entry method	• Manual entry of powder directly into the Hopper • Automated bag opener to transfer powder into Hopper. (accessory)	Manual entry of powder directly into the tank
Main Materials in Contact with Fluids	HDPE, EPDM, 316SS, PP, PE	HDPE, EPDM, 316SS, PP, PVC
Batch Verification	Measure Hydrostatic Pressure to indirectly calculate Specific Gravity (SG). Use of Powder manufacturer pass / fail SG data	User to manually measure SG and use Powder manufacturer pass / fail SG data to manually verify the solution

Technological Comparison to Predicate Device Specifications	Isopure Dry Acid Dissolution System	FMC Granuflo (Dry Acid Dissolution System)
	to automatically verify the solution	
Transfer Method	RFID connectors on transfer hose and holding tanks to verify that solution is transferred to the proper tank. Decision based on user predefined data.	Manual verification that the solution is transferred to the proper tank.
Record Keeping	System to maintain electronic records and print reports as paper back up	Paper Reports manually filled by users.

Non-Clinical Performance Data:

Verification and validation protocols were designed to test each function of the Isopure Dry Acid Dissolution System and ensure it performed as intended. Any errors or failures detected during testing were corrected. Materials of construction chosen were the same or even more inert than those of the predicate device. All materials found in water distribution loops have been evaluated for material compatibility with Dry Acid mixed solution. Standard use conditions in the dialysis water room environment were simulated for all testing that was conducted. Performance of control-related filling, pressure, and temperature sensors was tested to verify correct function in each of their respective system processes. A summary of the Non-Clinical Performance data can be seen in the table below

Testing provided results that the system was capable of mixing dry acid powder with purified water as intended and is capable to producing an acid concentrate solution consistent with the powder manufacturer's specifications.

Summary of Non-Clinical Performance Data

Test	Attachment	Description
Low and High Ends of Specific Gravity Range Mixing	X	Manufacturer pass/fail SG tables has min and max values for each prescription and different temperature points to accommodate variations in the manufacturing process. Bags could have more or less powder due to small variances in the process. The situation was simulated by adding or taking some powder away to come up with SG closer to the ranges provided by the

		manufacturer. These solutions were analyzed using the nominal SG/HP ratio calculated in the Low / Medium / High SG test to determine if the converted pass/fail table would still pass or reject batches as efficiently as the manufacturer's original pass/fail criteria.
Prescription Mixing	E	The test was used to verify the use of Hydrostatic Pressure (HP) as an indirect method of measuring HP and the use of a ratio between Specific Gravity (SG) and HP to convert SG pass/fail tables provided by the manufacturer to a HP table. Tests performed in low, medium and high end of the SG spectrum. The tests also went on to verify that the use of these ratios could determine that an acid batch that should not meet specifications, i.e. missing a bag, should result in a rejection for that batch. This verified that the method to determine a batch's quality by the mixer is as good as the powder manufacturer's original pass/fall criteria. The tests also verified repeatability of HP readings.
Small Scale Effects of Acid Powder on Temperature	S	This test determined how the water temperature would change once acid powder had been added, independent of the system itself. This was completed on a small scale, using mixing powder with 1 liter of water.
Large Scale Effects of Acid Powder on Temperature	T	This test determined how the water temperature would change when acid powder was added inside the system. It was completed using full sized batches inside the Isopure Dry Acid Dissolution System.
Effects of temperature on Hydrostatic Pressure (HP) Sensor	M	The system was challenged with incoming water pressures at the low and high ends of the manufacturer's recommended working temperatures (20° C and 30°C) to verify if the HP values would remain constant or if a temperature compensation algorithm would be required.
Self-Calibration	R	This test's purpose was to verify that the system could accommodate small variations in sensors over time and among different units in case of field replacements.

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Transfer Process	U	The test verified that the transfer process is a repeatable process that results in most of the end product being transferred from the mixer into a separate storage tank. The transfer process relies on the system reading the pressure at different points and estimating the time remaining based on the rate of emptying.
IFM Pressure sensor	N	This test's purpose was to verify linearity, accuracy and repeatability of the HP sensor.
IFM Temperature sensor	O	To verify linearity, accuracy and repeatability of the temperature sensor.
Fill Sensor	V	This test was used to verify the repeatability of the fill sensor (also called Capacitive Sensor).
Bag Opener Reliability	Z	This test's purpose was to verify general components reliability and that the contents of the bags are consistently and fully dispensed into the system. The test also identified MTBF values as well as process failure points.
Disinfection and Rinse	P	This test's purpose was to verify the methods used to incorporate Peracetic acid as a disinfectant into the system and the corresponding rinsing methodologies. No disinfection efficacy was tested assuming that the presence of the said agents for the recommended contact times sufficed to prove disinfection.
Microbiological Disinfection	Q	This test's purpose was to verify that the disinfection process for the Isopure Dry Acid Dissolution System achieves at least 3-log reduction of non-tuberculous bacteria and at least 6-log reduction of tuberculous bacteria within a maximum disinfection time of 60 minutes.
Leaching Analysis	J	Assuming that the mixed solution could stay inside the Mixing Tank for up to 2 weeks, the system was challenged under this scenario. Samples of the solutions pre and post exposure times were sent to an accredited laboratory for analysis. Generally accepted leaching studies were conducted.
Usability Engineering	L	This test's purpose was to analyze Human Factors normal Use Case scenarios were simulated after conducting a Task

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		Analysis. The main objective of the tests was to assess and mitigate Risks caused by Usability problems associated with the normal use of the device. Usability Goals were met, and Risk Scores associated with Usability Related Risks were acceptable according to Isopure's Risk Management SOP.
Noise Level	AA	This test's purpose was to verify that the noise produced by the system is kept below 90dB (excluding alert sounds)
Effects of Incoming Water Pressure on Fill Level	W	This test's purpose was to determine what effects, if any, the incoming water pressure has on the fill level sensor's performance.

Clinical Performance Data:
No clinical performance testing was required for determination of substantial equivalence of this type and class of device.

Conclusion:
The information and data provided in this 510(k) Notification establish that the Isopure Dry Acid Dissolution System is substantially equivalent to the legally marketed predicate device in relation to intended use, technological characteristics and operational characteristics.