October 13, 2017

Di-Chem, Inc.
Keith Buchholz
Compliance Manager
12297 Ensign Avenue North
Champlin, MN 55316

Re: K171015
Trade/Device Name: Citryte™ Acid Concentrate
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KPO
Dated: August 30, 2017
Received: September 7, 2017

Dear Keith Buchholz:

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 contact the Division of Industry and Consumer Education (DICE) 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. 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 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 Industry and Consumer Education (DICE) 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,

Joyce M. Whang -S

for 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

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)*
K171015

Device Name
Citryte™ Acid Concentrate

Indications for Use *(Describe)*
The Di-Chem, Inc. Citryte Acid Concentrate for bicarbonate dialysis is indicated for use in the treatment of acute and chronic hemodialysis. It is to be used with the appropriate hemodialysis machine and sodium bicarbonate concentrate.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SUBMITTER:	Di-Chem, Inc. 12297 Ensign Avenue North Champlin, MN 55311 Ph. 763-422-8311 Fax. 763-422-8472
510(k) #	K171015
FDA Registration	2183415
# Contact:	Keith Buchholz
DATE Revised:	August 9, 2017
DEVICE NAME:	Citryte™ Acid Concentrate
COMMON NAME:	Acid Concentrate for hemodialysis
CLASSIFICATION:	Class II per 21 CFR 876.5820 (Hemodialysis System and Accessories)
PRODUCT CODE:	KPO: Gastroenterology/Urology
PRIOR SUBMISSIONS:	There are no prior submissions for this device
PREDICATE DEVICES:	**Primary Predicate Devices:** Rockwell Medical Technologies CitraPure (K160847) Diasol Inc. Citrisol (K130511) **Reference Predicate Devices:** Advanced Renal Technologies Inc. (K980659) Di-Chem Inc. (K012328)

DEVICE DESCRIPTION:

The Di-Chem, Inc. proposed Citryte hemodialysis acid concentrate is provided in dry form and is for use in sodium bicarbonate dialysis. Citryte is comprised of sodium chloride (100.0mEq/L), potassium chloride (1.0-3.0mEq/L), calcium chloride (2.0-3.0mEq/L), magnesium chloride (1.0 mEq/L), dextrose (100 mg%), and citric acid (2.4mEq/L). All of the chemical constituents meet USP grade or equivalent. The proposed device will be manufactured, tested and labeled in accordance to ANSI/AAMI 13958:2014 guidelines. Each of the proposed formulations will be offered in three different mix volumes, 16.5 gallon, 20 gallon and 25 gallon to meet the three mix volume

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sizes of the current commercially available hemodialysis mixing machines. Each case of product contains the measured amount of each chemical component corresponding to the labeled product formula and listed final solution volume. The product packaging consists of two equal weight bags of sodium chloride, one bag of dextrose and one bag containing the citric acid, potassium chloride, calcium chloride and magnesium chloride. Each product bag is labeled indicating its contents, lot number, use by date, and product formula. The product bags are comprised of polyethylene and are 18"x24"x0.004". The four bags are then packaged into one corrugate box. Each box will contain all of the chemical components to make one of the three available volumes of the labeled formulation. The product is intended to be mixed into solution using water meeting or exceeding ANSI/AAMI Hemodialysis Water Quality Standards utilizing commercially available hemodialysis concentrate mixers in accordance with the mixer manufacturer's directions. These chemicals when in solution are intended to be used as the acid portion of a three part hemodialysis treatment in conventional commercially available hemodialysis machines or monitors in providing a hemodialysis treatment. The hemodialysis formulations presented in this 510(k) notification are intended to be used in a three-stream hemodialysis machine in which an acid concentrate (Citryte) is proportioned into one stream, a sodium bicarbonate concentrate solution is proportioned into another stream and a specified volume of water is proportioned into the remaining stream of the hemodialysis machines proportioning system. These three streams are then mixed by the hemodialysis machine to prepare a final proportioned hemodialysis solution. These proportioned hemodialysis solutions are then heated to body temperature and pumped through the hemodialysis compartment of a hemodialyzer (artificial kidney). These hemodialysis solutions are separated from the patient's blood by a semi-permeable cellulosic or non-cellulosic membrane which functions as a molecular weight selective barrier to the passage of molecules above a certain molecular weight. The semi-permeable membrane in the hemodialyzer permits the passage of both ionized and non-ionized molecules, waste products and toxins including blood urea, nitrogen, creatinine and potassium contained in the patient's blood circulating through the hemodialyzer to pass through the semi-permeable membrane into the hemodialysis solution then circulating back to the hemodialysis machine where the solution is ultimately discarded. The ionic and molecular composition of the hemodialysis solution establishes the concentration gradient between the patient's blood and the hemodialysis solution passing through the hemodialyzer which permits the effective removal of waste products and toxins found in excess in the patient's blood during acute and end-stage renal failure. Since different patients have different requirements for the removal rates and quantities of the various molecules and toxins in acute and end-stage renal failure it is necessary to have a variety of different hemodialysis solution formulations to satisfy the needs of all renal failure patients. For this reason the Citryte is offered in multiple formulations containing varying amounts of potassium chloride and calcium chloride.

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Citryte™ Ingredient Ranges

Criteria	Specification
Formulary Ingredient Range	**Sodium 100.0 mEq/L** **Calcium 2.0 - 3.0 mEq/L** **Potassium 1.0 - 3.0 mEq/L** **Magnesium 1.0 mEq/L** **Dextrose 100 mg/dl** **Citric Acid 2.4 mEq/L** **Acetate 0 - 0.3 mEq/L**
Concentrate Type	**Dry Powder Concentrate** **16.5gal, 20gal, 25gal kits**
Proportioning Ratio (Concentrate to Water)	**45X**

The Citryte™ acid concentrate formulas we plan to market upon acceptance of this 510(k) notification include the following. (Note: Any future new formulas within the previously approved predicate device ranges listed above will be implemented in accordance with our design control and maintained in accordance with our device design history files.)

Citryte™ Dry Acid Concentrate Formulas

Sodium 100.0mEq/L	Potassium 1.0-3.0 mEq/L	Calcium 2.0-3.0 mEq/L	Magnesium 1.0 mEq/L	Citric Acid 2.4mEq/L	Dextrose 100 mg%
100	1.0	2.0	1.0	2.4	100
100	1.0	2.5	1.0	2.4	100
100	2.0	2.0	1.0	2.4	100
100	2.0	2.25	1.0	2.4	100
100	2.0	2.5	1.0	2.4	100
100	2.0	3.0	1.0	2.4	100
100	3.0	2.0	1.0	2.4	100
100	3.0	2.5	1.0	2.4	100
100	3.0	3.0	1.0	2.4	100

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PREDICATE DEVICES (PRIMARY AND REFERENCE):
The Di-Chem, Inc. Citryte™ hemodialysis dry concentrate is substantially equivalent to the Rockwell Medical CitraPure® acid concentrate, the Diasol Citrisol acid concentrate, and the Advanced Renal Technologies DRYalysate acid concentrate.

INDICATIONS FOR USE:
Di-Chem, Inc. Citryte™ Acid Concentrate for Bicarbonate dialysis is indicated for use in the treatment of acute and chronic hemodialysis. It is to be used with the appropriate hemodialysis machine and sodium bicarbonate monitor.

This indications for use statement is essentially the same as the indications for use statement for the predicate devices.

TECHNOLOGICAL CHARACTERISTICS:
(PRIMARY PREDICATE DEVICES)
Comparing the proposed device to the primary predicate devices shows that they utilize the exact same range of chemical components, exact same packaging materials, and the exact same chemical formulations.
There are no significant differences.

(REFERENCE PREDICATE DEVICE DRYalysate)
Comparing the proposed device to the reference predicate device shows that they utilize a similar range of chemical components, exact same packaging materials, and similar chemical formulations. The only difference is the proposed Citryte device does not contain the 0.3mEq/L of sodium acetate that the DRYalysate reference predicate device does.

(REFERENCE PREDICATE DEVICE Hemo-Lyte Sodium Bicarbonate)
The Di-Chem Inc. Hemo-Lyte Sodium Bicarbonate for hemodialysis is being included as a reference predicate device because it is the other necessary component required to perform a hemodialysis treatment and shares the identical product packaging material in both size and polyethylene material and is sourced from the same suppliers as the proposed Citryte device.

SUMMARY OF NON-CLINICAL TESTS:
In vitro testing was performed to verify the chemical composition
of the proposed device was identical to that of the predicate devices and within the ranges set forth by ANSI/AAMI 13958:2014. Testing was performed in accordance with

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our standard operating procedures utilizing validated equipment and analytical methods. The results of the testing met the requirements of ANSI/AAMI 13958:2014 (Concentrates for Hemodialysis and Related Therapies) which specifies that all electrolytes identified on the device label shall be present within ±5% or ±0.1mEq/L and glucose within ±5% or ±0.05g/L (expressed as dialysis fluid concentrations), whichever is greater of the stated concentration, with the exception of sodium, which shall be present within ±2.5% of the labeled concentration. The results of these tests confirmed the proposed Citryte device met the listed range requirements stated in ANSI/AAMI 13958:2014 and is chemically equivalent to the predicate devices for all the listed chemical formulations.

CLINICAL TEST RESULTS:

Clinical testing was not performed.

SUBSTANTIAL EQUIVALENCE:

(PRIMARY PREDICATE DEVICES)

The proposed Di-Chem Citryte device is manufactured utilizing the same chemicals, formula composition ranges, packaging materials and intended use as the Rockwell Medical CitraPure and Diasol Citrisol primary predicate devices.

(REFERENCE PREDICATE DEVICE DRYalysate)

The proposed Di-Chem Citryte device is manufactured utilizing the same chemicals, formulation composition ranges, packaging materials and intended use as the Advanced Renal Technologies DRYalysate reference predicate devices with the only difference being the proposed Citryte device does not contain the 0.3mEq/L of sodium acetate that the DRYalysate reference predicate device does.

(REFERENCE PREDICATE DEVICE Hemo-Lyte Sodium Bicarbonate)

Sodium bicarbonate is the other necessary chemical component required to perform a hemodialysis dialysis treatment. The Hemo-Lyte sodium bicarbonate is manufactured in the same facility and uses the exact same polyethylene bag packaging material in the exact same size from the exact same suppliers as the proposed Citryte device.

CONCLUSIONS:

Comparing the proposed Citryte acid concentrate device to the predicate devices shows they are substantially equivalent in intended use, chemical composition, chemical formulations, packaging materials and device labeling.