



December 7, 2018

Global Scientific Technologies, LLC
William Griswold, Jr.
President
P.O Box 1347
Duncan, South Carolina 29334-1347

Re: K180679

Trade/Device Name: CitriCon Liquid and Powder (Acid Concentrate acidified with Citric Acid)
AcetiCon Liquid and Powder (Acid Concentrate acidified with either Acetic Acid or Sodium Di Acetate)
BicarboCon Liquid and Powder (Bicarbonate Concentrate)
RenaCon Liquid and Powder (Acetate Concentrate with Sodium Acetate)

Regulation Number: 21 CFR 876.5820

Regulation Name: Hemodialysis system and accessories

Regulatory Class: Class II

Product Code: KPO

Dated: November 5, 2018

Received: November 7, 2018

Dear William Griswold, Jr.:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 -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

Indications for Use

510(k) Number (if known)

K180679

Device Name

AcetiCon Liquid or Powder (Acid Concentrate acidified with either Acetic Acid or Sodium Di Acetate)

Indications for Use (Describe)

AcetiCon acid concentrate liquids or powders for bicarbonate dialysis are indicated for used in acute and chronic hemodialysis and are accessories to be used with the appropriate hemodialysis machine in a 3 stream mix in the exact prescribed proportion with ANSI/AAMI/ISO 13959 standard water for hemodialysis and with 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Indications for Use

510(k) Number (if known)

K180679

Device Name

CitriCon Liquid or Powder (Acid Concentrate acidified with Citric Acid and may be in combination with Sodium Acetate)

Indications for Use (Describe)

CitriCon acid concentrate liquids or powders for bicarbonate dialysis are indicated for used in acute and chronic hemodialysis and are accessories to be used with the appropriate hemodialysis machine in a 3 stream mix in the exact prescribed proportion with ANSI/AAMI/ISO 13959 standard water for hemodialysis and with 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)

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Indications for Use

510(k) Number (if known)

K180679

Device Name

BicarboCon Liquid or Powder (Bicarbonate Concentrate)

Indications for Use (Describe)

BicarboCon bicarbonate concentrate liquids or powders for bicarbonate dialysis are indicated for used in acute and chronic hemodialysis and are accessories to be used with the appropriate hemodialysis machine in a 3 stream mix in the exact prescribed proportion with ANSI/AAMI/ISO 13959 standard water for hemodialysis and with acid 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)

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Indications for Use

510(k) Number (if known)

K180679

Device Name

RenaCon Liquid or Powder (Acetate Concentrate with Sodium Acetate)

Indications for Use (Describe)

RenaCon acetate concentrate liquids or powders for acetate dialysis are indicated for used in acute and chronic hemodialysis and are accessories to be used with the appropriate hemodialysis machine in a 2 stream mix in the exact prescribed proportion with ANSI/AAMI/ISO 13959 standard water for hemodialysis.

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)

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Global Scientific Technologies, LLC
AcetiCon, CitriCon, BicarboCon & RenaCon for Hemodialysis (Liquids & Powders)
Traditional 510(k) Premarket Notification
510(k) SUMMARY UNDER 21 CFR 807.92

This 510(k) summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content in this 510(k) summary has been provided in conformance with 21 CFR Part 807.92.

1. Submitter's Information:

Company Name: Global Scientific Technologies, LLC

Physical Address: 151 Old Jones Road
City: Greer
State: South Carolina
Zip Code: 29651

Mailing Address: P.O. Box 1347
City: Duncan
State: South Carolina
Zip Code: 29334-1347

Contact Name: William J. Griswold, Jr.
Title: President
Office Phone: 864-655-3590
Fax: 877-655-3502

Preparation Date: March 12, 2018
Revision Date: November 5, 2018

2. Device Name (21 CFR 876.5820):

2.1. Dialysate Concentrate Solutions for Hemodialysis:

2.1.1. Acid Concentrate Liquids & Powders:

Trade Name(s): CitriCon & AcetiCon Acid Concentrate Liquids & Powders
Common/Usual Name: Dialysate Concentrate for Hemodialysis
Classification Name: Class II, Hemodialysis System and Accessories
Product Code: KPO: Gastroenterology/Urology

2.1.2. Acetate Concentrate Liquids & Powders:

Trade Name(s): RenaCon Acetate Concentrate Liquids & Powders
Common/Usual Name: Dialysate Concentrate for Hemodialysis
Classification Name: Class II, Hemodialysis System and Accessories
Product Code: KPO: Gastroenterology/Urology

Global Scientific Technologies, LLC
AcetiCon, CitriCon, BicarboCon & RenaCon for Hemodialysis (Liquids & Powders)
Traditional 510(k) Premarket Notification
510(k) SUMMARY UNDER 21 CFR 807.92

2.1.3. Bicarbonate Concentrate Liquids & Powders:

Trade Name(s): BicarboCon Bicarbonate Concentrate Liquids & Powders

Common/Usual Name: Dialysate Concentrate for Hemodialysis

Classification Name: Class II, Hemodialysis System and Accessories

Product Code: KPO: Gastroenterology/Urology

3. Predicate Device Names:

3.1. Solution Technologies – K982378 (PRIMARY PREDICATE)

3.1.1. Device Names: Hemosol, Hemogran, Nephrosol, Nephrogran, Bicarbosol and Bicarbogran Dialysate Concentrate

3.2. Rockwell Medical Technologies, Inc – K160847 & K062399 (SECONDARY PREDICATE)

3.2.1. Device Name: CitraPure Acid Concentrate

3.3. Advanced Renal Technologies, Inc – K000792 (SECONDARY PREDICATE)

3.3.1. Device Name: Citrasate Acid Concentrate

3.4. Diasol, Inc. – K130511 (SECONDARY PREDICATE)

3.4.1. Device Name: Citrisol Acid Concentrate

3.5. Di-Chem, Inc. – K171015 (REFERENCE DEVICE)

3.5.1. Device Name: Citryte Acid Concentrate

3.6. Di-Chem, Inc. – K012328 (REFERENCE DEVICE)

3.6.1. Device Name: Hemo-Lyte Bicarb Powder

3.7. Fresenius Medical Care North America – K070177 (REFERENCE DEVICE)

3.7.1. Fresenius Naturalyte Liquid Acid Concentrates, 9000, 6000 and 4000 Series

3.8. Fresenius Medical Care North America – K071387 (REFERENCE DEVICE)

3.8.1. Fresenius Naturalyte Sodium Bicarbonate Liquid Concentrates, 4000 Series

Global Scientific Technologies, LLC

AcetiCon, CitriCon, BicarboCon & RenaCon for Hemodialysis (Liquids & Powders)

Traditional 510(k) Premarket Notification

510(k) SUMMARY UNDER 21 CFR 807.92

4. Device Description / Indications for Use:

4.1. CitriCon and AcetiCon Liquid and Powder Acid Concentrates and BicarboCon Liquid and Powder Bicarbonate Concentrates:

4.1.1. Device Description – All liquid and powder acid and bicarbonate concentrates for bicarbonate dialysis presented in this 510(k) Notification are produced in a manner consistent with the predicate devices listed in Section 3 of this 510(k) Summary by adhering to strict cGMP guidelines and in accordance with AAMI/ANSI/ISO 13958:2014 Concentrates for Hemodialysis and Related Therapies and AAMI/ANSI/ISO 13959:2014 Water for Hemodialysis and Related Therapies. CitriCon liquids and powders contain Citric Acid and may contain Sodium Acetate along with various other ingredients (such as sodium chloride, calcium chloride, potassium chloride, magnesium chloride and dextrose, all meeting or exceeding current AAMI standards for purity) are equivalent to currently marketed acid concentrates for bicarbonate dialysis. AcetiCon liquids and powders contain either Acetic Acid or Sodium DiAcetate along with various other ingredients (such as sodium chloride, calcium chloride, potassium chloride, magnesium chloride and dextrose, all meeting or exceeding current AAMI standards for purity) are equivalent to currently marketed acid concentrates for bicarbonate dialysis. BicarboCon liquids and powders contain Sodium Bicarbonate and may contain Sodium Chloride, (both either meeting or exceeding current AAMI standards for purity) are equivalent to currently marketed bicarbonate concentrates for bicarbonate dialysis. These products are not designed and/or formulated for re-use and should be considered as single-use only. These acid and bicarbonate concentrate liquid and powder formulations when proportioned/mixed with pre-treated, purified water that meets or exceeds current AAMI standards may be used with conventional and commercially available hemodialysis machines or monitors as a hemodialysis solution. These hemodialysis concentrates are intended to be used in three stream hemodialysis machine in which an acidified concentrate is proportioned into one stream, a bicarbonate concentrate is proportioned into a second stream and a third stream of water that meets or exceeds current AAMI standards. Where these three streams are then mixed to prepare a final proportioned hemodialysis solution.

4.1.2. Summary of Concentrate Ranges:

4.1.2.1. AcetiCon Concentrates – Summary of Ranges:

Criteria	Description/Specification
Component Formula	Sodium 70 – 110 mEq/L
Range	Potassium 0 – 5 mEq/L
*Acetate is derived from either Acetic Acid or Sodium DiAcetate individually. Not in combination.	Calcium 0 – 5 mEq/L
	Magnesium 0 – 2 mEq/L
	Dextrose 0 – 350 mg/dl (mg %)
	*Acetate from Acetic Acid 2 – 5 mEq/L
	*Acetate from Sodium DiAcetate 4 – 8 mEq/L
Physical State	Liquid - packaged in Polyethylene (PE) containers Powder - packaged in Polyethylene (PE) containers
Proportioning Ratios (AcetiCon : Water)	1:34 (35X), 1:35.83 (36.83X), and 1:44 (45X)

Global Scientific Technologies, LLC
AcetiCon, CitriCon, BicarboCon & RenaCon for Hemodialysis (Liquids & Powders)
Traditional 510(k) Premarket Notification
510(k) SUMMARY UNDER 21 CFR 807.92

4.1.2.1.1. AcetiCon Concentrate Formulas:

The following lists of formulas for AcetiCon Concentrates, which are intend to market upon acceptance of this 510(k) submission, represent the most popular formulas within the component ranges submitted. Note: Any future new formulas within the approved ranges that are not listed herein will be documented using design controls and the design records will be maintained in the company's design history files.

Prod. Code	Na+ 70-110 mEq/L	K+ 0-5 mEq/L	Ca++ 0-5 mEq/L	Mg++ 0-2 mEq/L	Dextrose 0-350 mg %	Acetic Acid 2-5 mEq/L	Sodium DiAcetate 4-8 mEq/L
AC1000	79.00	2.00	3.50	1.50	0.00	4.00	
DA6000	79.00	2.00	3.50	1.50	0.00		8.00
AC1001	80.00	0.00	3.50	1.00	200.00	4.00	
DA6001	80.00	0.00	3.50	1.00	200.00		8.00
AC1003	80.00	2.00	3.50	1.00	200.00	4.00	
DA6003	80.00	2.00	3.50	1.00	200.00		8.00
AC1004	79.00	2.00	3.50	1.50	200.00	4.00	
DA6004	79.00	2.00	3.50	1.50	200.00		8.00
AC1006	79.00	2.00	2.50	1.50	100.00	4.00	
DA6006	79.00	2.00	2.50	1.50	100.00		8.00
AC1007	80.00	2.00	2.00	1.50	200.00	4.00	
DA6007	80.00	2.00	2.00	1.50	200.00		8.00
AC1008	80.00	2.50	3.50	1.00	150.00	4.00	
DA6008	80.00	2.50	3.50	1.00	150.00		8.00
AC1009	80.00	3.00	3.50	1.00	200.00	4.00	
DA6009	80.00	3.00	3.50	1.00	200.00		8.00
AC1015	80.00	2.00	2.50	1.00	200.00	4.00	
DA6015	80.00	2.00	2.50	1.00	200.00		8.00
AC1016	80.00	0.00	3.00	1.00	200.00	4.00	
DA6016	80.00	0.00	3.00	1.00	200.00		8.00
AC1017	80.00	2.00	2.20	1.50	200.00	4.00	
DA6017	80.00	2.00	2.20	1.50	200.00		8.00
AC1018	80.00	1.00	3.00	1.00	250.00	4.00	
DA6018	80.00	1.00	3.00	1.00	250.00		8.00
AC1019	79.00	0.00	3.50	1.50	0.00	4.00	
DA6019	79.00	0.00	3.50	1.50	0.00		8.00
AC1021	81.00	2.50	2.50	1.00	200.00	4.00	
DA6021	81.00	2.50	2.50	1.00	200.00		8.00
AC1025	81.00	2.00	3.25	0.50	0.00	4.00	
DA6025	81.00	2.00	3.25	0.50	0.00		8.00
AC1026	81.00	2.00	0.00	1.00	100.00	4.00	
DA6026	81.00	2.00	0.00	1.00	100.00		8.00

Global Scientific Technologies, LLC
AcetiCon, CitriCon, BicarboCon & RenaCon for Hemodialysis (Liquids & Powders)
Traditional 510(k) Premarket Notification
510(k) SUMMARY UNDER 21 CFR 807.92

Continuation of 4.1.2.1.1 AcetiCon Concentrate Formulas							
Prod. Code	Na+ 70-110 mEq/L	K+ 0-5 mEq/L	Ca++ 0-5 mEq/L	Mg++ 0-2 mEq/L	Dextrose 0-350 mg %	Acetic Acid 2-5 mEq/L	Sodium DiAcetate 4-8 mEq/L
AC1027	81.00	2.00	2.00	1.00	200.00	4.00	
DA6027	81.00	2.00	2.00	1.00	200.00		8.00
AC1029	81.00	2.00	2.50	1.00	200.00	4.00	
DA6029	81.00	2.00	2.50	1.00	200.00		8.00
AC1030	81.00	0.00	2.50	1.00	200.00	4.00	
DA6030	81.00	0.00	2.50	1.00	200.00		8.00
AC1031	81.00	2.00	3.00	1.00	200.00	4.00	
DA6031	81.00	2.00	3.00	1.00	200.00		8.00
AC1032	84.00	2.00	3.25	1.00	200.00	4.00	
DA6032	84.00	2.00	3.25	1.00	200.00		8.00
AC1033	84.00	1.00	2.50	1.00	200.00	4.00	
DA6033	84.00	1.00	2.50	1.00	200.00		8.00
AC1035	81.00	2.00	1.50	1.00	200.00	4.00	
DA6035	81.00	2.00	1.50	1.00	200.00		8.00
AC1036	81.00	3.00	2.50	0.50	100.00	4.00	
DA6036	81.00	3.00	2.50	0.50	100.00		8.00
AC1037	81.00	2.00	2.50	0.50	100.00	4.00	
DA6037	81.00	2.00	2.50	0.50	100.00		8.00
AC1038	80.00	3.00	3.00	1.00	200.00	4.00	
DA6038	80.00	3.00	3.00	1.00	200.00		8.00
AC1039	80.00	0.00	2.50	0.50	200.00	4.00	
DA6039	80.00	0.00	2.50	0.50	200.00		8.00
AC1040	80.00	2.00	2.50	0.50	200.00	4.00	
DA6040	80.00	2.00	2.50	0.50	200.00		8.00
AC1041	77.00	3.00	2.50	0.50	200.00	4.00	
DA6041	77.00	3.00	2.50	0.50	200.00		8.00
AC1042	80.00	2.00	3.00	1.00	200.00	4.00	
DA6042	80.00	2.00	3.00	1.00	200.00		8.00
AC1047	80.00	1.00	3.50	1.00	200.00	4.00	
DA6047	80.00	1.00	3.50	1.00	200.00		8.00
AC1048	80.00	3.00	2.00	1.00	200.00	4.00	
DA6048	80.00	3.00	2.00	1.00	200.00		8.00
AC1049	80.00	1.00	2.00	1.50	200.00	4.00	
DA6049	80.00	1.00	2.00	1.50	200.00		8.00
AC1050	84.00	1.00	3.00	1.00	200.00	4.00	
DA6050	84.00	1.00	3.00	1.00	200.00		8.00
AC1051	81.00	1.00	2.50	1.00	200.00	4.00	

Global Scientific Technologies, LLC
AcetiCon, CitriCon, BicarboCon & RenaCon for Hemodialysis (Liquids & Powders)
Traditional 510(k) Premarket Notification
510(k) SUMMARY UNDER 21 CFR 807.92

Continuation of 4.1.2.1.1 AcetiCon Concentrate Formulas							
Prod. Code	Na+ 70-110 mEq/L	K+ 0-5 mEq/L	Ca++ 0-5 mEq/L	Mg++ 0-2 mEq/L	Dextrose 0-350 mg %	Acetic Acid 2-5 mEq/L	Sodium DiAcetate 4-8 mEq/L
DA6051	81.00	1.00	2.50	1.00	200.00		8.00
AC1052	81.00	1.00	2.50	0.70	200.00	4.00	
DA6052	81.00	1.00	2.50	0.70	200.00		8.00
AC1053	81.00	0.00	0.00	1.00	200.00	4.00	
DA6053	81.00	0.00	0.00	1.00	200.00		8.00
AC1054	80.00	4.00	3.50	1.50	200.00	4.00	
DA6054	80.00	4.00	3.50	1.50	200.00		8.00
AC1055	83.00	0.00	0.00	1.00	200.00	4.00	
DA6055	83.00	0.00	0.00	1.00	200.00		8.00
AC1056	84.00	3.00	3.25	1.00	200.00	4.00	
DA6056	84.00	3.00	3.25	1.00	200.00		8.00
AC1057	84.00	2.00	1.00	1.00	200.00	4.00	
DA6057	84.00	2.00	1.00	1.00	200.00		8.00
AC1058	84.00	0.00	3.25	1.00	200.00	4.00	
DA6058	84.00	0.00	3.25	1.00	200.00		8.00
AC1059	81.00	3.00	2.50	0.75	200.00	4.00	
DA6059	81.00	3.00	2.50	0.75	200.00		8.00
AC1060	83.00	3.00	2.50	1.00	200.00	4.00	
DA6060	83.00	3.00	2.50	1.00	200.00		8.00
AC1061	80.00	3.00	2.50	0.75	200.00	4.00	
DA6061	80.00	3.00	2.50	0.75	200.00		8.00
AC1062	81.00	1.00	3.00	1.00	200.00	4.00	
DA6062	81.00	1.00	3.00	1.00	200.00		8.00
AC1063	70.00	1.00	5.00	0.00	200.00	2.00	
DA6063	70.00	1.00	5.00	0.00	200.00		4.00
AC1064	80.00	5.00	1.00	2.00	350.00	5.00	
DA6064	80.00	5.00	1.00	2.00	350.00		8.00
AC2000	100.00	2.00	3.00	0.75	0.00	4.00	
DA7000	100.00	2.00	3.00	0.75	0.00		8.00
AC2001	100.00	2.00	3.00	0.75	200.00	4.00	
DA7001	100.00	2.00	3.00	0.75	200.00		8.00
AC2002	100.00	0.00	3.00	0.75	200.00	4.00	
DA7002	100.00	0.00	3.00	0.75	200.00		8.00
AC2003	100.00	3.00	3.00	0.75	200.00	4.00	
DA7003	100.00	3.00	3.00	0.75	200.00		8.00
AC2006	100.00	1.00	3.00	0.75	200.00	4.00	

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DA7006	100.00	1.00	3.00	0.75	200.00		8.00
Continuation of 4.1.2.1.1 AcetiCon Concentrate Formulas							
Prod. Code	Na+ 70-110 mEq/L	K+ 0-5 mEq/L	Ca++ 0-5 mEq/L	Mg++ 0-2 mEq/L	Dextrose 0-350 mg %	Acetic Acid 2-5 mEq/L	Sodium DiAcetate 4-8 mEq/L
AC2007	100.00	2.00	0.00	0.75	200.00	4.00	
DA7007	100.00	2.00	0.00	0.75	200.00		8.00
AC2008	100.00	0.00	2.50	0.75	200.00	4.00	
DA7008	100.00	0.00	2.50	0.75	200.00		8.00
AC2011	100.00	1.00	0.00	0.75	200.00	4.00	
DA7011	100.00	1.00	0.00	0.75	200.00		8.00
AC2013	100.00	1.00	3.00	1.00	200.00	4.00	
DA7013	100.00	1.00	3.00	1.00	200.00		8.00
AC2017	100.00	2.00	2.00	0.75	200.00	4.00	
DA7017	100.00	2.00	2.00	0.75	200.00		8.00
AC2018	100.00	1.00	2.50	0.75	200.00	4.00	
DA7018	100.00	1.00	2.50	0.75	200.00		8.00
AC2019	100.00	2.00	2.50	0.75	200.00	4.00	
DA7019	100.00	2.00	2.50	0.75	200.00		8.00
AC2020	100.00	2.00	0.00	1.00	100.00	4.00	
DA7020	100.00	2.00	0.00	1.00	100.00		8.00
AC2021	100.00	1.00	2.00	1.00	200.00	4.00	
DA7021	100.00	1.00	2.00	1.00	200.00		8.00
AC2022	100.00	2.00	3.25	0.50	100.00	4.00	
DA7022	100.00	2.00	3.25	0.50	100.00		8.00
AC2023	100.00	3.00	2.00	0.75	200.00	4.00	
DA7023	100.00	3.00	2.00	0.75	200.00		8.00
AC2024	100.00	4.00	3.00	0.75	200.00	4.00	
DA7024	100.00	4.00	3.00	0.75	200.00		8.00
AC2025	100.00	1.50	2.50	0.75	200.00	4.00	
DA7025	100.00	1.50	2.50	0.75	200.00		8.00
AC2026	100.00	3.00	2.50	0.75	200.00	4.00	
DA7026	100.00	3.00	2.50	0.75	200.00		8.00
AC2027	100.00	0.00	0.00	0.75	200.00	4.00	
DA7027	100.00	0.00	0.00	0.75	200.00		8.00
AC3000	103.00	3.00	3.50	1.00	200.00	3.00	
DA8000	103.00	3.00	3.50	1.00	200.00		6.00
AC3001	103.00	2.00	3.50	1.00	100.00	3.00	
DA8001	103.00	2.00	3.50	1.00	100.00		6.00
AC3002	103.00	0.00	3.50	1.00	100.00	3.00	
DA8002	103.00	0.00	3.50	1.00	100.00		6.00

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AC3003	103.00	2.00	3.50	0.00	200.00	3.00	
Continuation of 4.1.2.1.1 AcetiCon Concentrate Formulas							
Prod. Code	Na+ 70-110 mEq/L	K+ 0-5 mEq/L	Ca++ 0-5 mEq/L	Mg++ 0-2 mEq/L	Dextrose 0-350 mg %	Acetic Acid 2-5 mEq/L	Sodium DiAcetate 4-8 mEq/L
DA8003	103.00	2.00	3.50	0.00	200.00		6.00
AC3004	103.00	1.00	3.50	1.00	200.00	3.00	
DA8004	103.00	1.00	3.50	1.00	200.00		6.00
AC3005	103.00	2.00	0.00	1.00	100.00	3.00	
DA8005	103.00	2.00	0.00	1.00	100.00		6.00
AC3006	103.00	2.00	3.50	1.00	200.00	3.00	
DA8006	103.00	2.00	3.50	1.00	200.00		6.00
AC3007	103.00	2.00	3.00	1.00	200.00	3.00	
DA8007	103.00	2.00	3.00	1.00	200.00		6.00
AC3008	103.00	3.00	3.00	1.00	200.00	3.00	
DA8008	103.00	3.00	3.00	1.00	200.00		6.00
AC3009	103.00	0.00	3.00	1.00	200.00	3.00	
DA8009	103.00	0.00	3.00	1.00	200.00		6.00
AC3010	103.00	2.00	1.00	1.00	200.00	3.00	
DA8010	103.00	2.00	1.00	1.00	200.00		6.00
AC3011	104.00	2.00	2.50	1.00	200.00	3.00	
DA8011	104.00	2.00	2.50	1.00	200.00		6.00
AC3012	103.00	2.00	2.00	1.00	200.00	3.00	
DA8012	103.00	2.00	2.00	1.00	200.00		6.00
AC3013	103.00	1.00	2.50	1.00	200.00	3.00	
DA8013	103.00	1.00	2.50	1.00	200.00		6.00
AC3014	103.00	2.00	2.50	0.75	100.00	3.00	
DA8014	103.00	2.00	2.50	0.75	100.00		6.00
AC3015	103.00	2.00	3.00	1.00	100.00	3.00	
DA8015	103.00	2.00	3.00	1.00	100.00		6.00
AC3016	103.00	2.00	2.50	0.75	200.00	3.00	
DA8016	103.00	2.00	2.50	0.75	200.00		6.00
AC3017	110.00	2.00	2.50	1.00	350.00	3.00	
DA8017	110.00	2.00	2.50	1.00	350.00		6.00
AC1XXX & DA6XXX series product code values are based on a proportion ratio of 1:35.83 (36.83X). AC2XXX & DA7XXX series product code values are based on a proportion ratio of 1:44 (45X). AC3XXX & DA8XXX series product code values are based on a proportion ratio of 1:34 (35X).							

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4.1.2.2. CitriCon Concentrates – Summary of Ranges:

Criteria	Description/Specification
Component Formula Range	Sodium 70 – 110 mEq/L Potassium 0 – 5 mEq/L Calcium 2 – 5 mEq/L *Citrate is derived from Citric Acid and acetate is derived from Sodium Acetate (which may be used in combination).
Physical State	Liquid - packaged in Polyethylene (PE) containers Powder - packaged in Polyethylene (PE) containers
Proportioning Ratios (CitriCon : Water)	1:34 (35X), 1:35.83 (36.83X), and 1:44 (45X)

4.1.2.2.1. CitriCon Concentrate Formulas:

The following lists of formulas for CitriCon Concentrates, which are intend to market upon acceptance of this 510(k) submission, represent the most popular formulas within the component ranges submitted. Note: Any future new formulas within the approved ranges that are not listed herein will be documented using design controls and the design records will be maintained in the company's design history files.

Prod. Code	Na+ 70-110 mEq/L	K+ 0-5 mEq/L	Ca++ 2-5 mEq/L	Mg++ 0-2 mEq/L	Dextrose 0-350 mg %	Citric Acid 2.4 mEq/L	Sodium Acetate 0-0.3 mEq/L
CC1000	79.00	2.00	3.50	1.50	0.00	2.40	0.00
CC1001	80.00	0.00	3.50	1.00	200.00	2.40	0.00
CC1003	80.00	2.00	3.50	1.00	200.00	2.40	0.00
CC1004	79.00	2.00	3.50	1.50	200.00	2.40	0.00
CC1006	79.00	2.00	2.50	1.50	100.00	2.40	0.00
CC1007	80.00	2.00	2.00	1.50	200.00	2.40	0.00
CC1008	80.00	2.50	3.50	1.00	150.00	2.40	0.00
CC1009	80.00	3.00	3.50	1.00	200.00	2.40	0.00
CC1015	80.00	2.00	2.50	1.00	200.00	2.40	0.00
CC1016	80.00	0.00	3.00	1.00	200.00	2.40	0.00
CC1017	80.00	2.00	2.20	1.50	200.00	2.40	0.00
CC1018	80.00	1.00	3.00	1.00	250.00	2.40	0.00
CC1019	79.00	0.00	3.50	1.50	0.00	2.40	0.00
CC1021	81.00	2.50	2.50	1.00	200.00	2.40	0.00
CC1025	81.00	2.00	3.25	0.50	0.00	2.40	0.00
CC1027	81.00	2.00	2.00	1.00	200.00	2.40	0.00
CC1029	81.00	2.00	2.50	1.00	200.00	2.40	0.00
CC1030	81.00	0.00	2.50	1.00	200.00	2.40	0.00
CC1031	81.00	2.00	3.00	1.00	200.00	2.40	0.00
CC1032	84.00	2.00	3.25	1.00	200.00	2.40	0.00
CC1033	84.00	1.00	2.50	1.00	200.00	2.40	0.00

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Continuation of 4.1.2.2.1 CitriCon Concentrate Formulas							
Prod. Code	Na+ 70-110 mEq/L	K+ 0-5 mEq/L	Ca++ 2-5 mEq/L	Mg++ 0-2 mEq/L	Dextrose 0-350 mg %	Citric Acid 2.4 mEq/L	Sodium Acetate 0-0.3 mEq/L
CC1036	81.00	3.00	2.50	0.50	100.00	2.40	0.00
CC1037	81.00	2.00	2.50	0.50	100.00	2.40	0.00
CC1038	80.00	3.00	3.00	1.00	200.00	2.40	0.00
CC1039	80.00	0.00	2.50	0.50	200.00	2.40	0.00
CC1040	80.00	2.00	2.50	0.50	200.00	2.40	0.00
CC1041	77.00	3.00	2.50	0.50	200.00	2.40	0.00
CC1042	80.00	2.00	3.00	1.00	200.00	2.40	0.00
CC1047	80.00	1.00	3.50	1.00	200.00	2.40	0.00
CC1048	80.00	3.00	2.00	1.00	200.00	2.40	0.00
CC1049	80.00	1.00	2.00	1.50	200.00	2.40	0.00
CC1050	84.00	1.00	3.00	1.00	200.00	2.40	0.00
CC1051	81.00	1.00	2.50	1.00	200.00	2.40	0.00
CC1052	81.00	1.00	2.50	0.70	200.00	2.40	0.00
CC1054	80.00	4.00	3.50	1.50	200.00	2.40	0.00
CC1056	84.00	3.00	3.25	1.00	200.00	2.40	0.00
CC1058	84.00	0.00	3.25	1.00	200.00	2.40	0.00
CC1059	81.00	3.00	2.50	0.75	200.00	2.40	0.00
CC1060	83.00	3.00	2.50	1.00	200.00	2.40	0.00
CC1061	80.00	3.00	2.50	0.75	200.00	2.40	0.00
CC1062	81.00	1.00	3.00	1.00	200.00	2.40	0.00
CC1063	70.00	1.00	5.00	0.00	200.00	2.40	0.00
CC1065	80.00	5.00	2.00	2.00	350.00	2.40	0.30
CC2000	100.00	2.00	3.00	0.75	0.00	2.40	0.00
CC2001	100.00	2.00	3.00	0.75	200.00	2.40	0.00
CC2002	100.00	0.00	3.00	0.75	200.00	2.40	0.00
CC2003	100.00	3.00	3.00	0.75	200.00	2.40	0.00
CC2006	100.00	1.00	3.00	0.75	200.00	2.40	0.00
CC2008	100.00	0.00	2.50	0.75	200.00	2.40	0.00
CC2013	100.00	1.00	3.00	1.00	200.00	2.40	0.00
CC2017	100.00	2.00	2.00	0.75	200.00	2.40	0.00
CC2018	100.00	1.00	2.50	0.75	200.00	2.40	0.00
CC2019	100.00	2.00	2.50	0.75	200.00	2.40	0.00
CC2021	100.00	1.00	2.00	1.00	200.00	2.40	0.00
CC2022	100.00	2.00	3.25	0.50	100.00	2.40	0.00
CC2023	100.00	3.00	2.00	0.75	200.00	2.40	0.00
CC2024	100.00	4.00	3.00	0.75	200.00	2.40	0.00
CC2025	100.00	1.50	2.50	0.75	200.00	2.40	0.00

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CC2026	100.00	3.00	2.50	0.75	200.00	2.40	0.00
Continuation of 4.1.2.2.1 CitriCon Concentrate Formulas							
Prod. Code	Na+ 70-110 mEq/L	K+ 0-5 mEq/L	Ca++ 2-5 mEq/L	Mg++ 0-2 mEq/L	Dextrose 0-350 mg %	Citric Acid 2.4 mEq/L	Sodium Acetate 0-0.3 mEq/L
CC3000	103.00	3.00	3.50	1.00	200.00	2.40	0.00
CC3001	103.00	2.00	3.50	1.00	100.00	2.40	0.00
CC3002	103.00	0.00	3.50	1.00	100.00	2.40	0.00
CC3003	103.00	2.00	3.50	0.00	200.00	2.40	0.00
CC3004	103.00	1.00	3.50	1.00	200.00	2.40	0.00
CC3006	103.00	2.00	3.50	1.00	200.00	2.40	0.00
CC3007	103.00	2.00	3.00	1.00	200.00	2.40	0.00
CC3008	103.00	3.00	3.00	1.00	200.00	2.40	0.00
CC3009	103.00	0.00	3.00	1.00	200.00	2.40	0.00
CC3011	104.00	2.00	2.50	1.00	200.00	2.40	0.00
CC3012	103.00	2.00	2.00	1.00	200.00	2.40	0.00
CC3013	103.00	1.00	2.50	1.00	200.00	2.40	0.00
CC3014	103.00	2.00	2.50	0.75	100.00	2.40	0.00
CC3015	103.00	2.00	3.00	1.00	100.00	2.40	0.00
CC3016	103.00	2.00	2.50	0.75	200.00	2.40	0.00
CC3017	110.00	2.00	2.50	1.00	350.00	2.40	0.30
CC1XXX series product code values are based on a proportion ratio of 1:35.83 (36.83X). CC2XXX series product code values are based on a proportion ratio of 1:44 (45X). CC3XXX series product code values are based on a proportion ratio of 1:34 (35X).							

4.1.2.3. BicarboCon Concentrates – Summary of Ranges:

Criteria	Description/Specification
Component Formula Range	Sodium 30 – 59 mEq/L Bicarbonate 30 – 39 mEq/L *Chloride 0 – 20 mEq/L * The Chloride component range is calculated since chlorides are contributed by another component.
Physical State	Liquid - packaged in Polyethylene (PE) containers Powder - packaged in Polyethylene (PE) containers
Proportioning Ratios (BicarboCon : Water)	1:19.13 (20.13X), 1:25.16 (26.16X) or 1:31.2 (32.2X), and 1:27.46 (28.46X)

4.1.2.3.1. BicarboCon Concentrate Formulas:

The following lists of formulas for BicarboCon Concentrates, which are intend to market upon acceptance of this 510(k) submission, represent the most popular formulas within the component ranges submitted. Note: Any future new formulas within the approved ranges that are not listed herein will be documented using design controls and the design records will be maintained in the company's design history files.

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Prod. Code Series	Sodium 30-59 mEq/L	Bicarbonate 30-39 mEq/L	Chloride 0-20 mEq/L	Proportion Ratio (BicarboCon : Water)
BC-1	59.00	39.00	20.00	1:19.13 (20.13X)
BC-2	37.00	37.00	0.00	1:25.16 (26.16X)
BC-2	30.00	30.00	0.00	1:31.20 (32.20X)
BC-3	35.00	35.00	0.00	1:27.46 (28.46X)

4.1.3. Indications for Use:

- 4.1.3.1.** AcetiCon acid concentrate powders and liquids for bicarbonate dialysis are indicated for use in acute and chronic hemodialysis and are accessories to be used with the appropriate hemodialysis machine in a 3 stream mix in the exact prescribed proportion with ANSI/AAMI/ISO 13959 standard water for hemodialysis and with bicarbonate concentrate.
- 4.1.3.2.** CitriCon acid concentrate powders and liquids for bicarbonate dialysis are indicated for use in acute and chronic hemodialysis and are accessories to be used with the appropriate hemodialysis machine in a 3 stream mix in the exact prescribed proportion with ANSI/AAMI/ISO 13959 standard water for hemodialysis and with bicarbonate concentrate.
- 4.1.3.3.** BicarboCon bicarbonate concentrate powders and liquids for bicarbonate dialysis are indicated for use in acute and chronic hemodialysis and are accessories to be used with the appropriate hemodialysis machine in a 3 stream mix in the exact prescribed proportion with ANSI/AAMI/ISO 13959 standard water for hemodialysis and with acid concentrate.

4.2. RenaCon Liquid and Powder Acetate Concentrates:

- 4.2.1. Device Description** - All liquid and powder acetate concentrates for acetate dialysis presented in this 510(k) Notification are produced in a manner consistence with the predicate devices listed in the Section 3 of this 510(k) Summary by adhering to strict cGMP guidelines and in accordance with AAMI/ANSI/ISO 13958:2014 Concentrates for Hemodialysis and Related Therapies and AAMI/ANSI/ISO 13959:2014 Water for Hemodialysis and Related Therapies. RenaCon liquids and powders contain Sodium Acetate along with various other ingredients (such as sodium chloride, calcium chloride, potassium chloride, magnesium chloride and dextrose, all meeting or exceeding current AAMI standards for purity) are equivalent to currently marketed acetate concentrates for acetate dialysis. These products are not designed and/or formulated for re-use and should be considered as single-use only. These acetate concentrate liquid and powder formulations when proportioned/mixed with pre-treated, purified water that meets or exceeds current AAMI standards may be used with conventional and commercially available hemodialysis machines or monitors as a hemodialysis solution. These hemodialysis concentrate formulas are intended to be used in two stream hemodialysis machine in which an acetate concentrate is proportioned into one stream and a second stream of water that meets or exceeds current AAMI standards.

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Where these two streams are then mixed to prepare a final proportioned hemodialysis solution.

4.2.2. Summary of Concentrate Ranges:

4.2.2.1. RenaCon Concentrates – Summary of Ranges:

Criteria	Description/Specification
Component Formula Range	Sodium 130 – 145 mEq/L Potassium 0 – 5 mEq/L Calcium 0 – 5 mEq/L Magnesium 0 – 2 mEq/L Dextrose 0 – 350 mg/dl (mg %) Sodium Acetate 33 – 45 mEq/L
Physical State	Liquid - packaged in Polyethylene (PE) containers Powder - packaged in Polyethylene (PE) containers
Proportioning Ratios (RenaCon : Water)	1:34 (35X)

4.2.2.1.1. RenaCon Concentrate Formulas:

The following lists of formulas for RenaCon Concentrates, which are intend to market upon acceptance of this 510(k) submission, represent the most popular formulas within the component ranges submitted. Note: Any future new formulas within the approved ranges that are not listed herein will be documented using design controls and the design records will be maintained in the company's design history files.

4.2.2.1.1. RenaCon Concentrate Formulas						
Prod. Code	Na+ 130-145 mEq/L	K+ 0-5 mEq/L	Ca++ 0-5 mEq/L	Mg++ 0-2 mEq/L	Dextrose 0-350 mg %	Sodium Acetate 33-45 mEq/L
SA5002	140.00	2.00	3.50	0.75	0.00	38.25
SA5004	140.00	2.00	3.50	1.00	200.00	35.00
SA5005	140.00	2.00	3.25	1.00	200.00	35.00
SA5006	134.00	2.60	2.50	1.50	250.00	36.60
SA5007	138.00	2.50	3.50	1.50	100.00	38.00
SA5010	135.00	1.00	3.50	1.00	0.00	36.00
SA5017	140.00	2.00	3.50	1.50	100.00	41.00
SA5024	140.00	3.00	3.50	1.50	100.00	41.00
SA5026	140.00	3.00	3.25	1.00	200.00	40.00
SA5027	135.00	2.50	3.25	1.50	100.00	37.00
SA5029	135.00	2.00	3.50	1.00	200.00	36.00
SA5034	135.00	2.00	3.50	1.50	200.00	37.00
SA5045	140.00	2.00	3.00	1.50	200.00	38.50
SA5046	132.00	2.00	3.50	1.50	200.00	35.00

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4.2.2.1.1. RenaCon Concentrate Formulas						
Prod. Code	Na+ 130-145 mEq/L	K+ 0-5 mEq/L	Ca++ 0-5 mEq/L	Mg++ 0-2 mEq/L	Dextrose 0-350 mg %	Sodium Acetate 33-45 mEq/L
SA5101	140.00	2.00	2.50	1.00	100.00	37.00
SA5102	130.00	0.00	5.00	2.00	100.00	33.00
SA5103	145.00	5.00	0.00	1.00	200.00	45.00
SA5104	134.00	2.00	3.00	0.00	350.00	35.00

4.2.3. Indication for Use:

4.2.3.1. RenaCon acetate concentrate powders and liquids for acetate dialysis are indicated for use in acute and chronic hemodialysis and are accessories to be used with the appropriate hemodialysis machine in a 2 stream mix in the exact prescribed proportion with ANSI/AAMI/ISO 13959 standard water for hemodialysis.

5. Comparison of Technological Characteristics with the Predicate Devices:

5.1. The Acid, Bicarbonate and Acetate Concentrates in both liquid and powder formats presented in this 510(k) Notification share the same technological characteristics of the predicate devices listed in Section 3 of this 510(k) Summary. These formulations are manufactured under the same cGMP Guideline and adhere to the same AAMI/ANSI/IOS Standards which regulate the manufacturing of concentration as well as determine the tolerance guidelines of each chemical component of the various formulations. Under these strict guidelines, standards have been established for all manufacturers of hemodialysis concentrate liquids and powers which are required to be followed. Thereby, providing the hemodialysis market a uniform standard of safety and effectiveness for hemodialysate concentrates. The acid and bicarbonate concentrates are used together in one of 4 industry standard mix ratios as determined by the hemodialysis machine's pump setting that allow for 3 streams (acid, bicarbonate and water). The acetate concentrates are used independently of the acid and bicarbonate concentrates and utilize a unique mix ratio available in 2 stream (acetate and water) hemodialysis machines. All formulations, within their respective mix ratios, are determined by the component concentration measured in milli-equivalents per liter as prescribed by physicians for a patient's optimum hemodialysis treatment. The industry standard for the packaging liquid and powder hemodialysis concentrates follows the guidelines found in ANSI/AAMI/ISO 13958:2014 Sec 4.1.10 Containers. The liquids will be packaged in the exact same high density polyethylene containers from the exact same suppliers as Solution Technologies' predicate device in various sizes such as 1 gallon jugs and 55 gallon drums. These liquid concentrates are ready for use by the appropriate hemodialysis machine with the same intended use. The powders are packaged in the exact same low density polyethylene bags from the exact same supplier as Di-Chem's reference devices in pre-measured amounts of the various chemical components to yield a pre-determined volume of hemodialysis concentrate liquid ready for use by the

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appropriate hemodialysis machine with the same intended use.

6. Performance Data for Safety and Effectiveness:

6.1. In vitro testing was performed on laboratory prepared formulations as instructed on the device labels which bracket the extremes of each critical component in each product line proposed in this submission to determine the individual component concentration to ensure that following the label instructions generates the concentrate formulation stated on the label. Testing was conducted using validated equipment and validated analytical methods. The acceptance criteria requirements of ANSI/AAMI 13958:2014 Concentrates for hemodialysis and related therapies, which are stated in sections 4.1.2.1 and 4.1.2.2 were followed for all components. In addition to the chemical concentration testing, both endotoxin and microbial testing was performed in accordance with ANSI/AAMI 13958:2014 sections 4.1.4 and 4.1.5 and in compliance with the release requirements in ANSI/AAMI 11663:2014 section 4.1.2. Product formulations were tested for endotoxins using a commercially available and validated Limulus Amebocyte Lysate (LAL) test. All endotoxin results reported levels well below the release limit of 0.5 EU/ml. Microbial testing was performed on all formulations containing bicarbonate. All microbial count results reported levels well below the release limit of 100 CFU/ml. The results of these test confirm that the performance of the proposed devices within this submission are satisfactory and substantially equivalent to the predicate devices for the same parameters.

7. Conclusion:

Since the cleared predicate devices listed are regulated by the same manufacturing standards and guidelines, have equivalent indication for use statements, use the same chemical components, the same chemical formulation ranges, follow the same label requirements for both liquid and powder hemodialysis concentrates, and use the same packaging materials and suppliers indicates that the proposed hemodialysis concentrate liquids and powders in this 510(k) Notification are believed to be substantially equivalent to the predicate devices in safety, effectiveness and performance as well as or better than the legally marketed predicate devices when used in accordance with the instructions for use.