



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 20, 2016

Rockwell Medical
Robert L. Chioini
CEO and President
30142 Wixom Road
Wixom, MI 48393

Re: K160847
Trade/Device Name: Rockwell Medical CitraPure® Acid Concentrates
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KPO
Dated: September 14, 2016
Received: September 16, 2016

Dear Robert L. Chioini:

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 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 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 -S

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)
K160847

Device Name
Rockwell Medical CitraPure® Acid Concentrates

Indications for Use (Describe)

The Rockwell Medical CitraPure® Acid Concentrates powders and liquids are indicated for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine/monitor and 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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510(k) Summary

Date Prepared: 9/14/16

Submitter: Rockwell Medical, Inc.
30142 Wixom Road
Wixom, MI 48393
Phone: 248-960-9009 Fax: 249-960-9119

Contact Name: Rob Chioini, CEO

Device Name: Rockwell Medical CitraPure[®] Acid Concentrates

Device Common Name: Dialysate Concentrate for Hemodialysis (liquid or powder)

Classification: Concentrate Solutions for Hemodialysis
Accessories to Hemodialysis
Class II, 78, KPO

Performance Standards: No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Class II Hemodialysis concentrate solutions and powders.

Predicate Device: Primary Predicate Devices:
Advanced Renal Technologies (ART) DRYalysate Acid Concentrates K980659

Advanced Renal Technologies (ART) Citrasate Acid Concentrates K000792

Reference Predicate Device:
Rockwell Medical CitraPure[®] Acid Concentrates K062399

Address, Registration # Address and registration number of the manufacturer sites:

Rockwell Medical
301 Wixom Road, Wixom, MI 48393
FDA Registration #: 1835498

Rockwell Medical
4051 Freeport Parkway, Grapevine, TX 76051
FDA Registration #: 1652176

Rockwell Medical
604 High Tech Court, Greer SC 29650
FDA Registration #: 1065847

Device Description:

The Rockwell Medical CitraPure® Acid Concentrates for Bicarbonate Dialysis are available in liquid and dry forms and contain salt, sugar, and non-sugar powders formulated and intended for use in hemodialysis when mixed or proportioned with the appropriate volume of purified water and bicarbonate concentrate / powder. These solutions and powders when proportioned and mixed with pre-treated or purified water meeting or exceeding AAMI Standards, may be used in conventional and commercially available hemodialysis machines or monitors as hemodialysis solution. The hemodialysis concentrate solutions and powders presented in this 510(k) Notification are intended to be used in three stream hemodialysis machines in which an acidified concentrate is proportioned into one stream, a bicarbonate concentrate solution prepared by mixing bicarbonate, chloride, and sodium concentrate with a specified volume of water is proportioned into the second stream, and purified water is proportioned into the third stream. These three streams are then mixed to prepare a final proportioned hemodialysis solution.

The CitraPure® series formulas are manufactured using the same validated processes, same packaging, and same USP grade ingredients. The only difference is that the raw material ingredient amounts are varied to create different formulas. This 510(k) notification establishes ranges for each concentrate ingredient, with the intent of creating different formulas by varying ingredient quantities within these established ranges using design control. Use of an approved dialysis concentrate formula range is necessary to permit the physicians flexibility to prescribe appropriate treatment meeting specific patient needs.

Table 1,
CitraPure® Ingredient Ranges

Criteria	Specification
Formulary Ingredient Range	Sodium 70 – 110.0 mEq/L Calcium 2.0 – 5.0 mEq/L Potassium 0.0 – 5.0 mEq/L Magnesium 0.0 – 2.0 mEq/L Dextrose 0 - 200 mg/dl Citric Acid 2.4 mEq/L Acetate 0 - 0.3 mEq/L
Concentrate Type	Liquid (gallons, drums) Dry powder concentrate (25 gal./kit)
Proportioning Ratios (Concentrate to Water)	1:35.83, 1:34.00, and 1:44.00

Traditional 510K Notification
Modification to CitraPure® Acid Concentrates for Bicarbonate Dialysis

The CitraPure® concentrate formulas we plan to market upon acceptance of this 510(k) include the following. Note: Any future new formulas within the approved ranges that are not on this list will be documented using design control and the design records will be maintained in our design history files.

Table 2
CitraPure® Concentrate Formulas

Na+ 70 - 110.0 mEq/L	K+ 0.0 - 5.0 mEq/L	Ca++ 2.0 - 5.0 mEq/L	Mg++ 0.0 - 2.0 mEq/L	Citric Acid 2.4 mEq/L	Dextrose 0.0- 200 mg%
100.00	1.00	2.00	1.00	2.40	100.00
100.00	2.00	2.00	1.00	2.40	100.00
100.00	3.00	2.00	1.00	2.40	100.00
100.00	1.00	2.50	1.00	2.40	100.00
100.00	2.00	2.50	1.00	2.40	100.00
100.00	3.00	2.50	1.00	2.40	100.00
100.00	2.00	3.00	1.00	2.40	100.00
100.00	2.00	3.50	1.00	2.40	100.00
100.00	3.00	3.00	1.00	2.40	100.00
100.00	2.00	2.50	1.00	2.40	200.00
100.00	2.00	2.25	1.00	2.40	100.00
100.00	4.00	3.00	1.00	2.40	100.00
100.00	2.50	2.50	1.60	2.40	100.00
100.00	2.50	2.25	1.30	2.40	100.00
80.00	2.00	2.00	1.50	2.40	100.00
80.00	4.00	2.50	1.00	2.40	100.00
80.00	3.00	2.50	1.00	2.40	100.00
81.00	1.00	2.50	1.00	2.40	100.00
81.00	2.00	2.50	1.00	2.40	100.00
80.00	2.00	3.50	1.00	2.40	100.00
103.00	2.00	2.50	1.00	2.40	100.00
100.00	2.00	2.75	1.00	2.40	100.00
100.00	3.00	2.75	1.00	2.40	100.00
100.00	3.00	2.25	1.00	2.40	100.00
100.00	2.00	3.25	1.00	2.40	100.00
100.00	3.00	3.25	1.00	2.40	100.00
80.00	2.00	3.50	1.00	2.40	200.00
81.00	2.00	2.50	1.00	2.40	200.00
81.00	2.00	3.00	1.00	2.40	200.00
103.00	3.00	2.50	1.00	2.40	200.00

Table 2 continued.
CitraPure® Concentrate Formulas

Na+	K+	Ca++	Mg++	Citric Acid	Dextrose
70 - 110.0 mEq/L	0.0 - 5.0 mEq/L	2.0 - 5.0 mEq/L	0.0 - 2.0 mEq/L	2.4 mEq/L	0.0- 200 mg%
100.00	2.00	3.00	0.75	2.40	80.00
80.00	2.00	3.50	1.00	2.40	80.00
100.00	2.00	2.50	0.75	2.40	0.00
80.00	2.00	3.50	1.00	2.40	0.00
100.00	5.00	2.50	0.75	2.40	100.00
100.00	0.00	2.50	0.75	2.40	100.00
100.00	2.50	5.00	0.75	2.40	100.00
100.00	2.50	2.50	0.00	2.40	100.00
100.00	2.50	2.50	2.00	2.40	100.00
70.00	2.50	2.00	0.75	2.40	100.00
110.00	2.50	2.00	0.75	2.40	100.00

Predicate Devices:

The Rockwell Medical CitraPure® hemodialysis concentrate powders and liquids with modified formulary ranges are substantially equivalent to the Rockwell Medical CitraPure® Acid Concentrates, Advanced Renal Technologies DRYalysate Acid Concentrates, and Advanced Renal Technologies Citrasate Acid Concentrates.

Indications for Use:

The Rockwell Medical CitraPure® Acid Concentrates powders and liquids are indicated for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine/monitor and bicarbonate concentrate.

This indication statement is essentially the same as the indication statement for the predicate device.

Technological Characteristics:

Comparing the proposed device to the predicate device, both devices utilize the same range of chemical compositions, same packaging, and same formulations. There are no significant differences.

Summary of Non-clinical Tests:

In vitro testing was performed to determine the chemical composition and range of composition. Testing was conducted per our Design Control processes, using

Modification to CitraPure® Acid Concentrates for Bicarbonate Dialysis

validated equipment and validated analytical methods. Acceptance criteria met requirements of ANSI/AAMI 13958, *Concentrates for hemodialysis and related therapies*, which specifies that all electrolytes identified on the label shall be present within $\pm 5\%$ or ± 0.1 mEq/l and glucose within $\pm 5\%$ or ± 0.05 g/l (expressed as dialysis fluid concentrations), whichever is greater, of the stated concentration, with the exception of sodium, which shall be present within $\pm 2.5\%$ of the labelled concentration. The results of these tests confirmed the proposed device is substantially equivalent to the predicate device for these parameters.

Clinical Test Results:

Clinical testing was not performed.

Conclusions:

Testing performed on the Rockwell Medical CitraPure® Acid Concentrate liquid and dry powders with modified formula ranges indicates it is safe, effective, and performed as well as the predicate device, when used in accordance with instructions for use.