March 6, 2018

Dimesol USA, LLC
% David M. Marcus, J.D., Ph.D.
Associate
McNees Wallace & Nurick LLC
21 East State Street, Suite 1700
Columbus, OH 43215

Re: K171750
Trade/Device Name: Citric Complete™ Dry Citric Acid
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KPO
Dated: February 1, 2018
Received: February 1, 2018

Dear David M. Marcus:

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.

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.

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,

Charles Viviano -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)*
K171750

Device Name
Citric Complete™ Dry Citric Acid

Indications for Use *(Describe)*
This acid concentrate product is formulated for use in acute and chronic hemodialysis and to be used in conjunction with MedicaLyte™ bicarbonate, or an equivalent bicarbonate labeled for use in acute and chronic hemodialysis and having the same composition as Medicalyte Bicarbonate™, in a 45x three-stream artificial kidney (hemodialysis) machine.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Dimesol USA, LLC
Dry Citric Acid for Hemodialysis (Powder)
"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.

A. Submitter's Information

(1) Name:	McNees Wallace & Nurick LLC
(2) Address:	21 East State St., Suite 1700, Columbus, OH 43215 USA
(3) Phone:	614-719-2856
(4) Fax:	614-469-4653
(5) Contact Person:	David M. Marcus, J.D., Ph.D.
(6) Preparation Date:	June 12, 2017
(7) Revised Submission Date:	January 30, 2018

On Behalf of Applicant Entity (owner of 510(k))

(1) Applicant Name:	Dimesol USA, LLC
(2) Applicant Address:	509 Fishing Creek Rd., Lewisberry, PA 17339 USA
(3) Applicant Phone:	717-938-8391
(4) Applicant Fax:	717-938-3957
(5) Establishment Reg. No:	1528807

B. Device Name

(1) Trade Name:	Citric Complete™ Dry Citric Acid
(2) Common Name:	Dialysis Concentrate for Hemodialysis (Powder) (Dry Citric Acid)
(3) Classification:	Class II, per 21 CFR 876.5820 (Hemodialysis system and accessories)
(4) Product Code:	KPO: Gastroenterology/Urology

C. Legally Marketed Predicate Devices

Rockwell Medical CitraPure® Acid Concentrate (K160847)
Diasol, Inc. Citrasol Acid Concentrate (K130511)
Dimesol USA, LLC MedicaLyte™ Bicarbonate Powder (K131202)

Dimesol USA, LLC
Dry Citric Acid for Hemodialysis (Powder)
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D. Device Description

The Citric Complete™ dry citric acid powder devices for citric acid concentrate dialysis are comprised of USP grade sodium chloride, USP grade magnesium chloride, USP grade calcium chloride, USP grade potassium chloride, USP grade dextrose, and USP grade citric acid. These products may be used in conventional, commercially available hemodialysis machines or monitors as one of the necessary components of three-component hemodialysis solution. The hemodialysis concentrate solutions presented in this 510(k) premarket notification are intended to be used in 45x three-stream hemodialysis machines in which bicarbonate concentrate is proportioned into one stream, a citric acid solution prepared from the Citric Complete™ dry citric acid powder is proportioned into a second stream, and water is proportioned into the third stream of the hemodialysis machine proportioning system. These three streams are then mixed by the hemodialysis machine to prepare the final proportioned hemodialysis solution. The final hemodialysis solution is separated from a patient's blood by semi-permeable membranes which permit the passage of waste products and toxins contained in the patient's blood circulating through the hemodialyzer, and such waste products and toxins pass through the semi-permeable membranes into, and exit with the hemodialysis solution. By such treatment, waste products and toxins are removed from the patient's blood during acute and end-stage renal failure.

E. Indications for Use

This acid concentrate product is formulated for use in acute and chronic hemodialysis and to be used in conjunction with MedicaLyte™ bicarbonate, or an equivalent bicarbonate labeled for use in acute and chronic hemodialysis and having the same composition as Medicalyte Bicarbonate™, in a 45x three-stream artificial kidney (hemodialysis) machine.

F. Technological Characteristics:

Comparing the proposed Citric Complete™ dry citric acid powder devices to the Rockwell Medical CitraPure® Acid Concentrates (K160847) predicate devices, the devices utilize the same chemical compositions and produce the same citric acid solutions for hemodialysis (as described in Table 1). There are no significant differences, and therefore a finding of substantial equivalence is appropriate.

Dimesol USA, LLC
Dry Citric Acid for Hemodialysis (Powder)
"Traditional" 510(k) Premarket Notification

510(K) SUMMARY UNDER 21 CFR 807.92

TABLE 1. Performance Comparison Table (Citric Acid Solutions Generated from Concentrate According to Label Directions)*

Device	Na[1]	Ca[1]	K[1]	Mg[1]	Citric Acid[1]	Dextrose[2]	**Rockwell Medical CitraPure® Acid Concentrates[3]**
DCA-200	100	2.5	2.0	1.0	2.4	100	D4116 Formulation 5
DCA-201	100	2.0	2.0	1.0	2.4	100	D4108 Formulation 2
DCA-202	100	2.5	1.0	1.0	2.4	100	Formulation 4
DCA-203	100	2.5	3.0	1.0	2.4	100	D4117 Formulation 6
DCA-206	100	3.0	2.0	0.75	2.4	200	*See* 510(k) Summary Table 1[4]
DCA-225	100	3.0	2.0	1.0	2.4	100	D4124 Formulation 7
DCA-226	100	2.0	3.0	1.0	2.4	100	D4110 Formulation 3
DCA-228	100	3.0	3.0	1.0	2.4	100	Formulation 9

*The Component and Yield columns apply equally to the Device and Predicate Device.

[1] mEq/L

[2] mg/dL

[3] Formulation references are to the row number of the 510(k) summary for K160847.

[4] Although this exact formulation is not disclosed in the itemized compositions, it is entirely within the ranges provided in Table 1 of the 510(k) summary for K160847.

Dimesol USA, LLC
Dry Citric Acid for Hemodialysis (Powder)
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Comparing the proposed Citric Complete™ dry citric acid powder devices to the Diasol, Inc. CitriSol Acid Concentrate (K130511) predicate devices, the devices utilize the same chemical compositions and produce the same citric acid solutions for hemodialysis (as described in Table 2). There are no significant differences, and therefore a finding of substantial equivalence is appropriate.

TABLE 2. Performance Comparison Table (Bicarbonate Stream Dialysate Generated from Concentrate According to Label Directions)*

Device	Na[1]	Ca[1]	K[1]	Mg[1]	Citric Acid[1]	Dextrose[2]	**Diasol, Inc. CitriSol Acid Concentrate**
DCA-200	100	2.5	2.0	1.0	2.4	100	CS45225-10DEX100
DCA-202	100	2.5	1.0	1.0	2.4	100	CS45125-10DEX100
DCA-203	100	2.5	3.0	1.0	2.4	100	CS45325-10DEX100
DCA-231	100	2.5	2.0	0.75	2.4	100	CS45225-75-DEX100

*The Component and Yield columns apply equally to the Device and Predicate Device.
[1] mEq/L
[2] mg/dL

Comparing the proposed Citric Complete™ dry citric acid powder devices to the MedicaLyte™ Bicarbonate Powder (K131202) predicate devices, the devices are packaged in identical low density polyethylene bags (same material composition and processing) from the same manufacturer (Elkay Plastics Co., Inc. located at 6000 Sheila Street, Commerce, California 90040). There are no significant differences, and therefore a finding of substantial equivalence is appropriate.

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Performance Testing:

Performance testing was conducted on three batches each of DCA-200, DCA-201, DCA-202, DCA-203, DCA-206, DCA-225, DCA-226, DCA-228, and DCA-231. Testing was accomplished by formulating the dialysis liquid concentrate pursuant to the instructions on the device labels, and measuring the concentrations of all components to ensure that following the label instructions generates the liquid concentrate specified on the label. All testing was conducted pursuant to ANSI/AAMI/ISO 13958:2014, specifically with reference to sections 4.1.2.2 and 4.1.2.1. One sample from each batch was tested (with multiple replicates for each sample tested per the validated test method). The concentrations were then averaged to determine average concentrations for each device. All samples of all batches of each device tested were within acceptable limits as set by ANSI/AAMI/ISO 13958:2014. Therefore, the performance of these devices is considered to be satisfactory.

Biocompatibility Testing:

The low density polyethylene bags were subjected to biocompatibility testing for cytotoxicity, sensitization and irritation. Testing was conducted in compliance with the ANSI/AAMI/ISO 10993 standards.

Cytotoxicity of substances extractable from the polyethylene bags was measured using the Minimal Essential Media Elution test following ANSI/AAMI/ISO 10993-05. An extract of the polyethylene bags was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. In three samples of extract from the low density polyethylene bags, no cell lysis or intractyoplasmic granules were detected, resulting in three individual scores, as well as an average score, of zero, which is within the acceptable level of two or less pursuant to ANSI/AAMI/ISO 10993-05. Therefore, the low density polyethylene bags are considered non-cytotoxic.

Guinea Pig Maximization Sensitization Testing was conducted following ANSI/AAMI/ISO 10993-10. Thirty-four guinea pigs were used for the study (twenty-two tested and twelve in the control group). The animals were dosed with formulations of either test or control solution in three phases (two inductions and one challenge). Dermal appearance at the dose sites was scored after challenge phase patch removal. The low density polyethylene bag extracts were graded for erythema and edema following the challenge phase. No positive results whatsoever were detected for the low density polyethylene bag extracts. Therefore, the data

indicates that the polyethylene bags do not cause sensitization reactions under the conditions of the study, and are considered non-sensitizing.

Intracutaneous Reactivity Irritation Testing (Rabbits) was conducted following ANSI/AAMI/ISO 10993-10. Three animals were used for the study. The low density polyethylene bag extracts were intracutaneously injected. Each site was graded for tissue reaction. The low density polyethylene bag extracts were graded for erythema and edema, with the final score determined by scoring each injection site, and subtracting the score of the control from the test article score. The final score for the low density polyethylene bag extracts was well below the standard limit. Therefore, the low density polyethylene bags are considered non-irritants.

Endotoxin Analysis on Device Contents:

Endotoxin analysis was performed on each device. Testing was performed in accordance with ANSI/AAMI/ISO 13958:2014 section 4.1.2, under which the limit for endotoxins is 0.5 endotoxin units/mL or less. One sample from each of three batches of each device was tested (with multiple replicates for each sample tested per the validated test method). The standard is drafted for final dialysate rather than concentrate, which required further dilution of the concentrate prepared according to the instructions of the device label to overcome inhibition and enhancement due to the testing methodology. The standard dialysis fluid generated from the devices is well within the acceptable limits.

G. Conclusion

The Citric Complete™ dry citric acid powder devices are believed to be substantially equivalent in design, materials, and indications for use to the commercially available Rockwell Medical CitraPure® Acid Concentrates (K160847) predicate devices, the Diasol, Inc. CitriSol Acid Concentrate (K130511) predicate devices, and the MedicaLyte™ Bicarbonate Powder (K131202) predicate devices, and are therefore expected to be as safe, as effective, and perform as well as the predicate devices.