November 25, 2020

Nipro Renal Solutions Corporation USA
% David Marcus
Associate
McNees Wallace & Nurick LLC
21 East State Street, Suite 1700
Columbus, OH 43215

Re: K193155
Trade/Device Name: Nipro Dry Complete Dry Acid Concentrate for Hemodialysis
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KPO
Dated: October 29, 2020
Received: October 30, 2020

Dear David 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. 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

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)*
K193155

Device Name
Nipro Dry Complete™ Dry Acid Concentrate for Hemodialysis

Indications for Use *(Describe)*
For DA-100 series:

This acid concentrate product is formulated for use in acute and chronic hemodialysis and to be used in conjunction with MedicaLyteTM bicarbonate, or an equivalent bicarbonate labeled for use in acute and chronic hemodialysis and having the same composition as MedicaLyteTM bicarbonate, in a 36.83X three-stream artificial kidney (hemodialysis) machine.

-or-

For DA-200 series:

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

-or-

For DA-300 series:

This acid concentrate product is formulated for use in acute and chronic hemodialysis and to be used in conjunction with MedicaLyteTM bicarbonate, or an equivalent bicarbonate labeled for use in acute and chronic hemodialysis and having the same composition as MedicaLyteTM bicarbonate, in a 35X 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.

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Nipro Renal Solutions Corporation USA

Nipro Dry Complete™ Dry Acid Concentrate for Hemodialysis

"Traditional" 510(k) Premarket Notification – K193155

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:	November 11, 2019
(7) Revised Preparation Date:	October 29, 2020

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

(1) Applicant Name:	Nipro Renal Solutions Corporation USA
(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:	Nipro Dry Complete™ Dry Acid Concentrate for Hemodialysis
(2) Common Name:	Dialysis Concentrate for Hemodialysis (Dry 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

Nipro Renal Solutions Corporation USA MedicaPure™ Liquid Acid Concentrate (K901471)
Diasol, Inc. Dryasol Acid Concentrate Mix (K993212)
Nipro Renal Solutions Corporation USA MedicaLyte™ Bicarbonate Powder (K131202)

Nipro Renal Solutions Corporation USA
Nipro Dry Complete™ Dry Acid Concentrate for Hemodialysis
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D. Device Description

The Nipro Dry Complete™ dry acid concentrate devices for hemodialysis 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 acetic 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, and are formulated for 36.83X (DA-100 series), 45X (DA-200 series), and 35X (DA-300 series) proportioning dialysis machines. The hemodialysis concentrate solutions presented in this 510(k) premarket notification are intended to be used in an appropriately proportioned three-stream hemodialysis machines (36.83X, 45X, or 35X as specified on the device label) in which bicarbonate concentrate is proportioned into one stream, an acid solution prepared from the Nipro Dry Complete™ dry acid concentrate device 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 the 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 the hemodialysis solution and exit the hemodialyzer 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

For DA-100 series:

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 36.83X three-stream artificial kidney (hemodialysis) machine.

-or-

For DA-200 series:

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

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use in acute and chronic hemodialysis and having the same composition as MedicaLyte™ bicarbonate, in a 45X three-stream artificial kidney (hemodialysis) machine.

-or-

For DA-300 series:

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 35X three-stream artificial kidney (hemodialysis) machine.

F. Technological Characteristics:

Comparing the proposed Dry Complete™ dry acid concentrate devices to the MedicaPure™ Liquid Acid Concentrate (K901471) predicate devices, the devices utilize the same chemical compositions and produce the same acid solutions for hemodialysis. The devices also utilize substantially equivalent high density polyethylene bottles, which are made by the same manufacturing process with the same resin by the same manufacturer (CKS Packaging located at 943 Trollingwood Rd., Haw River, North Carolina 27258). The only difference between the bottles of the MedicaPure™ Liquid Acid Concentrate predicate devices (K901471) and the bottles of the proposed Dry Complete™ dry acid concentrate devices is the size of the bottles, which does not present any new hazard to the patients. Thus, there are no significant differences, and a finding of substantial equivalence is appropriate.

Comparing the proposed Nipro Dry Complete™ dry acid concentrate devices to the Diasol, Inc. Dryasol Acid Concentrate Mix (K993212) predicate devices, the devices utilize the same chemical compositions and produce the same acid concentrates for hemodialysis for thirty-three of the seventy-three proposed devices (with the other proposed devices being substantiated by K901471 as described above). There are no significant differences, and therefore a finding of substantial equivalence is appropriate.

Comparing the proposed Dry Complete™ dry acid concentrate devices to the MedicaLyte™ Bicarbonate Powder (K131202) predicate devices, the powder components of 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,

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Commerce, California 90040). There are no significant differences, and therefore a finding of substantial equivalence is appropriate.

Performance Testing:

Performance testing was conducted on three batches each of DA-100, DA-104, DA-106, DA-113, DA-115, and DA-118 for 36.83X proportioning systems; DA-210, DA-211, DA-213, DA-229, and DA-234 for 45X proportioning systems; and DA-303, DA-307, DA-308, and DA-314 for 35X proportioning systems. These formulations encompass the entire range of the chemical components present in the devices for each proportioning system and were thus determined to be representative of the proposed formulations. 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. 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.

Transportation testing per ASTM D4169-16 has been completed, including environmental conditioning, per ISTA Procedure 3A:2018, simulated distribution cycle testing, and inner package integrity testing. The results indicate that the proposed devices can be shipped and transported so that they may be received and used in a safe and effective way.

Biocompatibility was evaluated for the low density polyethylene bags and high density polyethylene bottles in accordance with Use of International Standard ISO 19003-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."

Endotoxin Analysis on Device Contents:

Endotoxin analysis was performed on three batches each of DA-100, DA-104, DA-106, DA-113, DA-115, and DA-118 for 36.83X proportioning systems; DA-210, DA-211, DA-213, DA-229, and DA-234 for 45X proportioning systems; and DA-303, DA-307, DA-308, and DA-314 for 35X proportioning systems. These formulations encompass the entire range of the chemical components present in the devices for each proportioning system and were thus determined to be representative of the proposed formulations. 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. The standard dialysis fluid generated from the devices was well within the acceptable limits.

Sterilization and Shelf Life

The devices are not provided in sterilized form, and the devices are non-sterile when used. Stability testing was conducted on aged samples.

All chemistry and bioburden stability testing on aged product was performed to conform to standards as laid out in ANSI/AAMI/ISO 13958:2014, Concentrates for haemodialysis and related therapies. Additionally, the aged product tested well within endotoxin specifications for safe release of this product. Results from package integrity testing were analyzed and accepted based on Acceptance Quality Limit (AQL) criteria developed using ISO 2859-1:2011, Sampling Procedures for Inspection by Attributes, Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-Lot Inspection.

G. Conclusion

The proposed Nipro Dry Complete™ dry acid concentrate devices are believed to be substantially equivalent in design, materials, and indications for use to the commercially available Nipro Renal Solutions Corporation USA MedicaPure™ Liquid Acid Concentrate (K901471) predicate devices, Diasol, Inc. Dryasol Acid Concentrate Mix (K993212) predicate devices, and Nipro Renal Solutions Corporation USA MedicaLyte™ Bicarbonate Powder (K131202) predicate devices, and are therefore expected to be as safe, as effective, and perform as well as the predicate devices.