August 4, 2023

Nipro Renal Solutions USA, Corp.
Vincent DeGrandchamp
Quality Assurance Manager
509 Fishing Creek Road
Lewisberry, Pennsylvania 17339

Re: K223431
Trade/Device Name: Citric Complete™ Liquid Citric Acid Concentrate
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Received: July 7, 2023

Dear Vincent DeGrandchamp:

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,

Gema Gonzalez -S

Gema Gonzalez, MS
Acting 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223431

Device Name

Citric Complete™ Liquid Citric Acid Concentrate

Indications for Use *(Describe)*

For LC+100 Series: This acid concentrate is formulated for use in acute and chronic hemodialysis, and is to be used in conjunction with Nipro MedicaLyte™ bicarbonate concentrate, or an equivalent bicarbonate concentrate of the same composition, in a 36.83X proportioning three-stream hemodialysis machine.

For LC+200 Series: This acid concentrate is formulated for use in acute and chronic hemodialysis, and is to be used in conjunction with Nipro MedicaLyte™ bicarbonate concentrate, or an equivalent bicarbonate concentrate of the same composition, in a 45X proportioning three-stream 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.

510(k) #: K223431

510(k) Summary

Prepared on: 2023-07-07

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Nipro Renal Solutions USA, Corporation
Applicant Address	509 Fishing Creek Road Lewisberry PA 17339 United States
Applicant Contact Telephone	2676784390
Applicant Contact	Mr. Vincent DeGrandchamp
Applicant Contact Email	VincentG@nipromed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Citric Complete™ Liquid Citric Acid Concentrate
Common Name	Hemodialysis system and accessories
Classification Name	Dialysate Concentrate For Hemodialysis (Liquid Or Powder)
Regulation Number	876.5820
Product Code	KPO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K160847	CitraPure® Acid Concentrate	KPO
K130511	CitriSol Acid Concentrate	KPO
K901471	GC-1000 to GC-3005 Acid Concentrate (MedicaPure™ Liquid Ac	KPO
K171750	Citric Complete™ Dry Citric Acid Concentrate	KPO

Device Description Summary

21 CFR 807.92(a)(4)

The Citric Complete™ Liquid Citric Acid Concentrate products are single-use, non-sterile devices intended for use in hemodialysis therapy for acute and chronic renal failure. These products are designed to be used as one (1) component in the preparation of dialysate in a three (3)-stream proportioning hemodialysis machine according to a physician's prescription.

The subject devices are formulated to be compatible with 36.83X proportioning (proposed LC+100 series devices), as well as 45X proportioning (proposed LC+200 series devices) hemodialysis machines, in which bicarbonate concentrate is proportioned into one stream, this Citric Complete™ Liquid Acid Concentrate is proportioned into a second stream, and RO water is proportioned into the third stream. These three streams are then mixed by the hemodialysis machine in distinctly specific ratios to prepare the final proportioned hemodialysis solution, or final dialysate.

The Citric Complete™ Liquid Citric Acid Concentrate products 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.

The final dialysate solution is pumped through a component of the dialysis system, known as the dialyzer or hemodialyzer, through which the patient's blood also flows in the opposite direction. The dialysate is separated from the patient's blood by semi-permeable membranes in the hemodialyzer, which permits the passage of waste and toxins from the circulating blood into the hemodialysis solution. The used dialysate is disposed, while the patient's blood is recirculated back into the patient. By such treatment, a patient with acute and end-stage renal failure can effectively have their blood filtered of wastes and toxins without the proper functioning of his or her kidneys.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

For LC+100 Series: This acid concentrate is formulated for use in acute and chronic hemodialysis, and is to be used in conjunction with Nipro MedicaLyte™ bicarbonate concentrate, or an equivalent bicarbonate concentrate of the same composition, in a 36.83X proportioning three-stream hemodialysis machine.

For LC+200 Series: This acid concentrate is formulated for use in acute and chronic hemodialysis, and is to be used in conjunction with Nipro MedicaLyte™ bicarbonate concentrate, or an equivalent bicarbonate concentrate of the same composition, in a 45X proportioning three-stream hemodialysis machine.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device as well as the predicate and reference devices are all acid concentrates formulated for use in acute and chronic hemodialysis as one component in a three-stream dialysate. There are no significant differences with respect to any of the above presented predicate devices in regard to their indications for use, and no new issues of safety or effectiveness of the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

Internal verification and validation testing confirms that the Citric Complete™ Liquid Citric Acid Concentrate meets specifications equivalent in design and technological characteristics to the predicate devices. The subject device complies with all applicable voluntary consensus standards for performance, package integrity and biocompatibility.

There are no significant differences with respect to any of the above presented predicate devices, and therefore a finding of substantial equivalence is deemed appropriate for the proposed Citric Complete™ Liquid Citric Acid Concentrate.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

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 by following the label instructions, end users can generate a final dialysate consistent with the values as specified on the Citric Complete™ Liquid Citric Acid Concentrate label. All testing was conducted pursuant to ANSI/AAMI/ISO 23500-4:2019. All requirements were met.

N/A

All samples from all batches of each device tested were within acceptable limits for that product, as set by ANSI/AAMI/ISO 23500-4:2019. Therefore, the performance of these devices is considered to be satisfactory, fit for use according to the intended purpose of this device., and as safe, as effective, and performing as well as or better than the legally marketed device K171750.