May 8, 2020

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Senior Director, Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Re: K192209
Trade/Device Name: Citrasate Dry Acid Concentrate,
Granuflo Dry Acid Concentrate
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: April 7, 2020
Received: April 8, 2020

Dear Denise Oppermann:

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)*
K192209

Device Name
Citrasate® Dry Acid Concentrate
GranuFlo® Dry Acid Concentrate

Indications for Use *(Describe)*
Citrasate® Dry Acid Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. Citrasate® Dry Acid Concentrate is intended to be used as one component in the preparation of dialysate in a 3-stream proportioning hemodialysis machine according to a physician's prescription.

GranuFlo® Dry Acid Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. GranuFlo® Dry Acid Concentrate is intended to be used as one component in the preparation of dialysate in a 3-stream proportioning hemodialysis machine according to a physician's prescription.

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.

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5. 510(K) SUMMARY

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

5.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 996-9103
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs – Devices
Preparation Date:	13 August 2019

5.2. Device Name

Trade Name:	Citrasate® Dry Acid Concentrate GranuFlo® Dry Acid Concentrate
Regulation Name:	Hemodialysis system and accessories
Regulatory Class:	Class II per 21 CFR § 876.5820
Product Code:	KPO
Product Code Name:	Dialysate Concentrate for Hemodialysis (Liquid or Powder)
Classification Panel:	Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

The legally marketed predicate device for the Citrasate Dry Acid Concentrate is the DRYalysate Concentrate cleared under K980659. The legally marketed predicate device for the GranuFlo Dry Acid Concentrate is the Naturalyte Granuflo Dry Acid Concentrate cleared under K030497.

GranuFlo Dry Acid Concentrate is currently subject to an open recall (Z-0516-2019, Z-0517-2019, and Z-0518-2019). Destruction of the product is in progress. After destruction, closure of the recall will be requested.

In March 2012, a Class I recall was initiated for FMCRTG acid concentrate products regarding total buffer prescribing information. Concerns arose due to the contribution of acetate in acid concentrates in addition to the prescribed bicarbonate. This contribution was later determined to present a lower patient risk than initially understood. Through a series of Pre-Submission (Q131379) correspondence, FMCRTG and FDA came to an agreement on a final warning statement for acid concentrate labeling in June 2018.

5.4. Device Description

5.4.1. Device Identification- Citrasate

Citrasate Dry Acid Concentrate product line consists of eight (8) formulations which differ in potassium chloride and calcium chloride mass. These dry components are packaged in four (4) flexible, laminated, sealed, and low-density polyethylene-based bags. These bags are designed to be mixed together using a Fresenius Medical Care Dry Acid Dissolution Unit (K131611). A list of the available Citrasate Dry Acid Concentrate products is provided in Table 1.

Table 1: Citrasate Dry Acid Concentrate Products

Part Number	Part Number Description
0FD1231-DA	Citrasate Dry Acid – 1.0 K, 2.25 Ca, 1.0 Mg
0FD1251-DA	Citrasate Dry Acid – 1.0 K, 2.5 Ca, 1.0 Mg
0FD2231-DA	Citrasate Dry Acid – 2.0 K, 2.25 Ca, 1.0 Mg
0FD2251-DA	Citrasate Dry Acid – 2.0 K, 2.5 Ca, 1.0 Mg
0FD2301-DA	Citrasate Dry Acid – 2.0 K, 3.0 Ca, 1.0 Mg
0FD3231-DA	Citrasate Dry Acid – 3.0 K, 2.25 Ca, 1.0 Mg
0FD3251-DA	Citrasate Dry Acid – 3.0 K, 2.5 Ca, 1.0 Mg
0FD3301-DA	Citrasate Dry Acid – 3.0 K, 3.0 Ca, 1.0 Mg

5.4.2. Device Identification- GranuFlo

GranuFlo Dry Acid Concentrate product line consists of nine (9) formulations which differ in potassium chloride and calcium chloride mass. GranuFlo Dry Acid Concentrate components are packaged in three (3) flexible, laminated, sealed, and low-density polyethylene-based bags. The bags' contents are designed to be mixed together using a Fresenius Medical Care Dry Acid Dissolution Unit (K131611). A list of the available GranuFlo Dry Acid Concentrate products is provided in Table 2.

Table 2: GranuFlo Dry Acid Concentrate Products

Part Number	Part Number Description
0FD1251-3B	GranuFlo Dry Acid – 1.0 K, 2.5 Ca, 1.0 Mg
0FD2201-3B	GranuFlo Dry Acid – 2.0 K, 2.0 Ca, 1.0 Mg
0FD2231-3B	GranuFlo Dry Acid – 2.0 K, 2.25 Ca, 1.0 Mg
0FD2251-3B	GranuFlo Dry Acid – 2.0 K, 2.5 Ca, 1.0 Mg
0FD2301-3B	GranuFlo Dry Acid – 2.0 K, 3.0 Ca, 1.0 Mg
0FD3201-3B	GranuFlo Dry Acid – 3.0 K, 2.0 Ca, 1.0 Mg
0FD3231-3B	GranuFlo Dry Acid – 3.0 K, 2.25 Ca, 1.0 Mg
0FD3251-3B	GranuFlo Dry Acid – 3.0 K, 2.5 Ca, 1.0 Mg
0FD3301-3B	GranuFlo Dry Acid – 3.0 K, 3.0 Ca, 1.0 Mg

5.4.3. Device Characteristics

Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate products are intended for use in hemodialysis therapy for acute and chronic renal failure. Both products consist of electrolytes (chloride salts of sodium, calcium, magnesium, and potassium), dextrose, and an organic acid source (citric acid in Citrasate; sodium diacetate in GranuFlo). Citrasate also contains sodium acetate as a secondary pH adjuster.

Citrasate Dry Acid Concentrate is a single use, non-sterile, device offered in 8 formulations which differ in potassium chloride and calcium chloride mass. The product components are contained in a four-bag packaging system. These bags are designed to be mixed together using a Fresenius Medical Care Dry Acid Dissolution Unit (K131611).

GranuFlo Dry Acid Concentrate is a single use, non-sterile, device offered in 9 formulations which differ in potassium chloride and calcium chloride mass. The product components are contained in a three-bag packaging system. These bags are designed to be mixed together using a Fresenius Medical Care Dry Acid Dissolution Unit (K131611).

5.4.4. Environment of Use

Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate are used in environments where acute and chronic hemodialysis is performed.

5.4.5. Brief Written Description of the Device

Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate are each intended to be used as one component in the preparation of dialysate in a 3-stream proportioning hemodialysis machine according to a physician's prescription. Both concentrates are formulated for use in 45X proportioning systems which proportion a nominal ratio of 1 : 1.72 : 42.28 (acid : bicarbonate : water) to generate dialysate. The dialysate is intended to be pumped through a dialyzer, creating

an osmotic gradient across the dialyzer membrane to exchange solutes with blood during hemodialysis.

5.4.6. Materials of Use

Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate are classified as externally communicating, blood path indirect, prolonged contact (>24 hours to 30 days) duration, Class II (Category B) devices in accordance with FDA guidance document *Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* (16 June 2016). The Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate bag packaging is composed of PVDC-coated PET/LLDPE film.

Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate are composed of USP grade raw chemicals or equivalent.

5.4.7. Key Performance Specifications/Characteristics

Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate are each used as a component of the dialysate for hemodialysis treatments. Both concentrates are intended to be used in 45X proportioning systems which proportion a nominal ratio of 1 : 1.72 : 42.28 (acid : bicarbonate : water) using water that meets ISO 13959 or ANSI/AAMI RD62 requirements to generate dialysate.

5.5. Intended Use

Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate are each intended for use in hemodialysis therapy for acute and chronic renal failure.

5.6. Indications for Use

Citrasate® Dry Acid Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. Citrasate® Dry Acid Concentrate is intended to be used as one component in the preparation of dialysate in a 3-stream proportioning hemodialysis machine according to a physician's prescription.

GranuFlo® Dry Acid Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. GranuFlo® Dry Acid Concentrate is intended to be used as one component in the preparation of dialysate in a 3-stream proportioning hemodialysis machine according to a physician's prescription.

5.7. Comparison of Technological Characteristics with the Predicate Device

The Citrasate Dry Acid Concentrate is substantially equivalent to the predicate DRYalysate Concentrate (K980659), and the GranuFlo Dry Acid Concentrate is substantially equivalent to the predicate Naturalyte Granuflo Dry Acid Concentrate (K030497) with regard to the following technological characteristics:

- Intended use

- Design
- Principle of operation
- Materials of construction
- Performance specifications

5.8. Performance Data

Performance testing was conducted for the Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate products. Results of performance testing support substantial equivalence, safety, and efficacy of the Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate.

5.8.1. Stability Design Verification

Stability evaluations were conducted for Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate to support the 24-month (2-year) shelf life. Stability is monitored as part of routine production testing. The 24-month shelf life is supported by real time stability evaluations.

5.8.2. Shipping Verification

Shipping and distribution verification testing was performed for the Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate products in accordance with *ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems*. Results support that the products' packaging is able to withstand the distribution environment.

5.8.3. Biocompatibility Testing

The following endpoints were assessed to support the biological safety of the Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate:

- Chemical characterization
- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Material mediated pyrogenicity
- Hemocompatibility

A toxicological risk assessment was also performed.

5.8.4. Human Factors Validation Testing

The Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate were validated for their safe and effective use in accordance with FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016).

5.8.5. Electrical Safety and Electromagnetic Compatibility

Not applicable. The Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate are not electrical mechanical devices.

5.8.6. Software Verification and Validation Testing

Not applicable. The Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate do not contain software.

5.8.7. Animal Studies

No animal studies were performed for Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate.

5.8.8. Clinical Studies

No clinical studies were performed for Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate.

5.9. Conclusions

The intended use, design, principle of operation, and materials of construction of the Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate are substantially equivalent to those of the predicate devices. Differences between the Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate and the predicates do not raise new concerns with regard to safety or efficacy. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, Citrasate Dry Acid Concentrate and GranuFlo Dry Acid Concentrate are safe and effective for their intended use.