February 24, 2020

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

Re: K191474
Trade/Device Name: NaturaLyte Dry Bicarbonate Concentrate (Rx-10 Bag)
NaturaLyte Dry Bicarbonate Concentrate (Rx-12 Bag)
NaturaLyte Dry Bicarbonate Concentrate (Carton)
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KPO
Dated: June 3, 2019
Received: June 4, 2019

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)*
K191474

Device Name
NaturaLyte® Dry Bicarbonate Concentrate (Rx-10 Bag), NaturaLyte® Dry Bicarbonate Concentrate (Rx-12 Bag), NaturaLyte® Dry Bicarbonate Concentrate (Carton)

Indications for Use *(Describe)*
NaturaLyte® Dry Bicarbonate Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. NaturaLyte® Dry Bicarbonate 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:	03 June 2019

5.2. Device Name

Trade Name:	NaturaLyte® Dry Bicarbonate Concentrate (Rx-10 Bag), NaturaLyte® Dry Bicarbonate Concentrate (Rx-12 Bag), NaturaLyte® Dry Bicarbonate Concentrate (Carton)
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 is the Biosol Bicarbonate Powder Concentrate (K981043). This device is not currently subject to a design-related recall.

5.4. Device Description

5.4.1. Device Identification

The NaturaLyte Dry Bicarbonate Concentrate is available in three (3) presentations based on the desired volume of bicarbonate concentrate. The 4879 g presentation yields 15.85 gallons (60 liters) and the 7807 g presentation yields 25.36 gallons (96 liters) and are supplied in bag-style packaging. The 650 g presentation, used for preparation of individual batches, yields 2.1 gallons (8.0 liters) of bicarbonate concentrate and is supplied in carton-style packaging. The available NaturaLyte Dry Bicarbonate Concentrate products are provided in Table 1.

Table 1: NaturaLyte Dry Bicarbonate Concentrate Products

Product Line	Part Number	Part Number Description
NaturaLyte Dry Bicarbonate Concentrates	08-4110-6	NaturaLyte Dry Bicarbonate, 4879 g (Rx-10 bag)
	08-4112-2	NaturaLyte Dry Bicarbonate, 7807 g (Rx-12 bag)
	08-4400-1	NaturaLyte Dry Bicarbonate, 650 g (carton)

5.4.2. Device Characteristics

NaturaLyte Dry Bicarbonate Concentrate is a non-sterile, single use device composed of United States Pharmacopeia (USP) grade sodium bicarbonate. NaturaLyte Dry Bicarbonate Concentrate products are packaged in either bags or cartons. The two (2) bag configurations are constructed from identical materials and only differ in the mass of dry bicarbonate powder contained within. The cartons are used for preparation of individual batches of bicarbonate concentrate.

5.4.3. Environment of Use

NaturaLyte Dry Bicarbonate Concentrate is used in environments where acute and chronic hemodialysis is performed.

5.4.4. Brief Written Description of the Device

NaturaLyte Dry Bicarbonate Concentrate is composed of sodium bicarbonate powder and is used as one component in the preparation of dialysate in a 3-stream proportioning hemodialysis machine according to a physician's prescription. NaturaLyte Dry Bicarbonate Concentrate is 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.

5.4.5. Materials of Use

NaturaLyte Dry Bicarbonate Concentrate is classified as an externally communicating, blood path indirect, prolonged contact (>24 hours to 30 days) duration, Class II (Category B) device 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 NaturaLyte Dry Bicarbonate Concentrate packaging is composed of the following materials:

- Bag (4879 g or 7807 g)- 9-layer nylon/polyethylene (PE) coextruded film
- Carton- solid bleached sulfate (SBS) 100% virgin fiberboard substrate, coated on both sides with low-density polyethylene (LDPE)

5.4.6. Key Performance Specifications/Characteristics

NaturaLyte Dry Bicarbonate Concentrate is packaged dry sodium bicarbonate which is used as a component of the dialysate for hemodialysis treatments. The dry sodium bicarbonate is intended to be mixed with water that meets ISO 13959 or ANSI/AAMI RD62 requirements. Once mixed with water according to the instructions for use, NaturaLyte Dry Bicarbonate Concentrate is intended to be used in 45X proportioning systems which proportion a nominal ratio of 1 : 1.72 : 42.28 (acid : bicarbonate : water) to generate dialysate.

5.5. Intended Use

NaturaLyte Dry Bicarbonate Concentrate is intended for use in hemodialysis therapy for acute and chronic renal failure.

5.6. Indications for Use

NaturaLyte® Dry Bicarbonate Concentrate is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. NaturaLyte® Dry Bicarbonate 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 NaturaLyte Dry Bicarbonate Concentrate is substantially equivalent to the predicate Biosol Bicarbonate Powder Concentrate (K981043) 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 NaturaLyte Dry Bicarbonate Concentrate products. Results of performance testing support substantial equivalence, safety, and efficacy of the NaturaLyte Dry Bicarbonate Concentrate.

5.8.1. Stability Design Verification

Stability evaluations were conducted for NaturaLyte Dry Bicarbonate Concentrate in support of 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 NaturaLyte Dry Bicarbonate Concentrate product in accordance with *ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems*. Results support that the product's 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 NaturaLyte Dry Bicarbonate Concentrate (bags and cartons):

- 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 NaturaLyte Dry Bicarbonate Concentrate was validated for its 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 NaturaLyte Dry Bicarbonate Concentrate is not an electrical mechanical device.

5.8.6. Software Verification and Validation Testing

Not applicable. The NaturaLyte Dry Bicarbonate Concentrate does not contain software.

5.8.7. Animal Studies

No animal studies were performed for NaturaLyte Dry Bicarbonate Concentrate.

5.8.8. Clinical Studies

No clinical studies were performed for NaturaLyte Dry Bicarbonate Concentrate.

5.9. Conclusions

The intended use, design, principle of operation, and materials of construction of the NaturaLyte Dry Bicarbonate Concentrate are substantially equivalent to that of the predicate device.

Differences between the NaturaLyte Dry Bicarbonate Concentrate and the predicate 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, NaturaLyte Dry Bicarbonate Concentrate is safe and effective for its intended use.