January 29, 2026

Fresenius Medical Care Renal Therapies Group, LLC
Laura Reed
Director, Submissions Management & RA In-Center
920 Winter St.
Waltham, Massachusetts 02451

Re: K253462
Trade/Device Name: NaturaLyte® Dry Bicarbonate Concentrate (08-4112-2)
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System And Accessories
Regulatory Class: Class II
Product Code: KPO
Dated: October 7, 2025
Received: October 7, 2025

Dear Laura Reed:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MAURA ROONEY -S

Maura Rooney
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.

510(k) Number *(if known)*
K253462

Device Name
NaturaLyte® Dry Bicarbonate Concentrate (08-4112-2)

Indications for Use *(Describe)*
NaturaLyte® Dry Bicarbonate Concentrate (08-4112-2) is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure. NaturaLyte® Dry Bicarbonate Concentrate (08-4112-2) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1. 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.

1.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Contact Person:	Laura Reed, Regulatory Affairs Director
Phone:	(781) 491-7581
Fax:	(781) 699-9635
Alternate Contact:	Denise Oppermann, Vice President Regulatory Affairs – North America
Phone:	(781) 996-9103
Preparation Date:	07 October 2025

1.2. Device Name

Trade Name:	NaturaLyte® Dry Bicarbonate Concentrate (08-4112-2)
Common Name:	Dry Bicarbonate 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)
FDA Review Panel:	Gastroenterology/Urology

1.3. Legally Marketed Predicate Device

The legally marketed predicate device is the NaturaLyte® Dry Bicarbonate Concentrate (08-4112-2) (K191474). This predicate has not been subject to a design-related recall.

1.4. Device Description

1.4.1. Device Identification

The NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) is composed of dry sodium bicarbonate. NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) is available in a 7807 g presentation that yields 25.36 gallons (96 liters) of bicarbonate concentrate volume. The 7807 g NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) is supplied in bag-style packaging.

1.4.2. Device Characteristics

The NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) is a non-sterile, single use Class II medical device composed of United States Pharmacopeia (USP) grade sodium bicarbonate.

1.4.3. Environment of Use

NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) is used in environments where acute and chronic hemodialysis is performed.

1.4.4. Brief Written Description of the Device

NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) 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 (08-4112-2) 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.

1.4.5. Materials of Use

NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) is classified as an externally communicating, blood path indirect, long-term contact (>30 days) duration, Class II (Category C) device in accordance with FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (08 September 2023).

The primary packaging for the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) is a bag that consists of a 9-layered coextruded film. The external layer is nylon, the six (6) internal layers are polyolefins and nylon, and the interior (seal) layer is two (2) linear low-density polyethylene (LLDPE) resins which have been blended together.

1.4.6. Key Performance Specifications/Characteristics

NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) 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 23500-3 or ANSI/AAMI RD62 requirements. Once mixed with water according to the instructions for use, NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) 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.

1.5. Intended Use

NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) is intended for use in hemodialysis therapy for acute and chronic renal failure.

1.6. Indications for Use

NaturaLyte® Dry Bicarbonate Concentrate (08-4112-2) is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute and chronic renal failure.

NaturaLyte® Dry Bicarbonate Concentrate (08-4112-2) 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.

1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) are substantially equivalent to those of the predicate NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) (K191474):

- Intended Use
- Indications for Use
- Design
- Materials
- Principle of Operation
- Performance Requirements

1.8. Performance Data

Performance testing was conducted for the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2). Results of performance testing support the safety and efficacy of the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) as well as its substantial equivalence to the predicate. Testing conducted to support the determination of substantial equivalence is summarized in Table 1.

Table 1: Performance Testing Summary

Test	Test Objective
Bicarbonate Assay	Determine bicarbonate concentration in mEq/L after NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) has been dissolved according to instructions for use.
Dissolution	Demonstrate that sodium bicarbonate dissolves in water through visual inspection.
Endotoxin	Determine endotoxin levels in EU/mL after NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) has been dissolved according to instructions for use.
Bioburden	Determine bioburden levels in CFU/mL after NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) has been dissolved according to instructions for use.
Seal Strength	Evaluate the bag seal strength of the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) through a creep-to-burst test.
Package Integrity by Visual Inspection	Ensure that the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) bag is intact and does not show any defects. Ensure that the label remains legible.
Package Integrity – Ink Migration	Evaluate package integrity of the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) bag after distribution simulation.
Film Comparison Testing	Evaluate the comparative performance of the current and proposed NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) bag films.

1.8.1. Stability Design Verification

Stability evaluations were conducted for NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) in support of the 3-month shelf life.

1.8.2. Shipping Verification

Shipping and distribution verification testing for the NaturaLyte Dry Bicarbonate Concentrate was conducted in accordance with *ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems*.

1.8.3. Biocompatibility Testing

Biocompatibility testing for the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) was conducted in accordance with ISO 10993-1:2018 and 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*" (08 September 2023). The following endpoints were evaluated to support the biological safety of the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2):

- Cytotoxicity, MTT Cytotoxicity Assay
- Sensitization, ISO Guinea Pig Sensitization Maximization
- Irritation, ISO Intracutaneous Irritation
- Material-mediated Pyrogenicity, USP Pyrogen Study

- Hemocompatibility, ASTM Hemolysis Extract
- Systemic Toxicity
- Genotoxicity
- Carcinogenicity
- Chemical Characterization

A toxicological risk assessment was also performed.

1.8.4. Human Factors Validation

Validation testing was not required. The NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) was found to be safe and effective for its intended users, uses, and use environments (K191474).

1.8.5. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) is not an electrical mechanical device.

1.8.6. Software Verification and Validation Testing

Not applicable. The NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) does not contain software.

1.8.7. Animal Studies

No animal studies were performed for NaturaLyte Dry Bicarbonate Concentrate (08-4112-2).

1.8.8. Clinical Studies

No clinical studies were performed for NaturaLyte Dry Bicarbonate Concentrate (08-4112-2).

1.9. Conclusion

The intended use, design, materials, and principle of operation of the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) are substantially equivalent to those of the predicate device. Test results demonstrate that the differences between the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) and predicate device 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, the NaturaLyte Dry Bicarbonate Concentrate (08-4112-2) is safe and effective for its intended use.