September 9, 2025

Fresenius Medical Care Renal Therapies Group, LLC
Timothy Groves
Regulatory Affairs Senior Lead
920 Winter Street
Waltham, Massachusetts 02451

Re: K252180
Trade/Device Name: Bicarby Dialysate RFP-404 (RFP-404-W); Bicarby Dialysate RFP-403 (RFP-403-W); Bicarby Dialysate RFP-403 (RFP-403-G); Bicarby Dialysate RFP-453 (RFP-453-W); Bicarby Dialysate RFP-453 (RFP-453-G); Bicarby Dialysate RFP-454 (RFP-454-W); Bicarby Dialysate RFP-454 (RFP-454-G); Bicarby Dialysate RFP-456 (RFP-456-W)
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System And Accessories
Regulatory Class: Class II
Product Code: KPO
Dated: July 11, 2025
Received: July 11, 2025

Dear Timothy Groves:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252180

Please provide the device trade name(s).

Bicarby Dialysate RFP-404 (RFP-404-W);
Bicarby Dialysate RFP-403 (RFP-403-W);
Bicarby Dialysate RFP-403 (RFP-403-G);
Bicarby Dialysate RFP-453 (RFP-453-W);
Bicarby Dialysate RFP-453 (RFP-453-G);
Bicarby Dialysate RFP-454 (RFP-454-W);
Bicarby Dialysate RFP-454 (RFP-454-G);
Bicarby Dialysate RFP-456 (RFP-456-W)

Please provide your Indications for Use below.

Bicarby™ Dialysate solutions are indicated for use as a dialysis fluid for adult patients in acute care settings, requiring Kidney Replacement Therapies (KRT).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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
Phone:	(781) 460-1087
Fax:	(781) 699-9635
Contact Person:	Timothy Groves, Senior Lead
Preparation Date:	11 July 2025

1.2. Device Name

Trade Names:	Bicarby™ Dialysate
Common Name:	Dialysis Solutions for Kidney Replacement Therapy (KRT)
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 for the proposed Bicarby Dialysate solutions is the Bicarby and Ci-Ca Dialysate solutions (K243786). These devices are not currently subject to any design-related recalls.

The Fresenius pureFLOW dialysis solutions (K233950), B. Braun Modified Duosol Bicarbonate Dialysate (K052393), Baxter PrismaSATE solutions (K162887), and NxStage PureFlow solutions (K053286) are used as reference devices.

1.4. Device Description

1.4.1. Device Identification

1.4.1.1. Bicarby Dialysate Solutions

The Bicarby Dialysate solutions are single-use, sterile, ready-to-use dialysis solutions consisting of sodium chloride, potassium chloride, magnesium chloride, calcium chloride (select solutions), sodium bicarbonate, and glucose. One (1) new calcium-containing solution and seven (7) new calcium-free solutions are being introduced. Of the 7 calcium-free solutions, there are only four (4) unique formulations (Table 1).

Table 1: Proposed Bicarby Dialysate Solutions

Proposed P/N (St. Wendel)	Proposed P/N (Guadalajara)	Proposed Brand Name	Solution Type
RFP-404-W	N/A[1]	Bicarby™ Dialysate RFP-404	Calcium-containing
RFP-403-W	RFP-403-G	Bicarby™ Dialysate RFP-403	Calcium-free
RFP-453-W	RFP-453-G	Bicarby™ Dialysate RFP-453	Calcium-free
RFP-454-W	RFP-454-G	Bicarby™ Dialysate RFP-454	Calcium-free
RFP-456-W	N/A[1]	Bicarby™ Dialysate RFP-456	Calcium-free

[1] RFP-404-G and RFP-456-G were cleared under K243786.

1.4.2. Environment of Use

The Bicarby Dialysate solutions are used in acute care environments where KRT is performed.

1.4.3. Brief Written Description of the Device

Bicarby Dialysate solutions are sterile dialysates for use in KRT. The solutions are each provided in a 2-compartment bag. One compartment contains 4.75 L of a slightly alkaline bicarbonate solution and the other compartment contains 0.25 L of an acidic electrolyte, glucose solution. The 2 solutions are mixed before use by opening the peel seam between the compartments, yielding 5 L of a ready-to-use sterile solution. The dialysate bags are made of a gas barrier foil, a material manufactured without PVC, latex, or plasticizer. The calcium-containing solutions are designed for modalities using heparin anticoagulation, while the calcium-free solutions are intended for modalities using regional citrate anticoagulation (RCA). The calcium-free solutions sustain the anticoagulatory effect of citrate in the filter. Therefore, a separate infusion of calcium is mandatory when using these solutions.

1.4.4. Materials of Use

The Bicarby Dialysate solutions 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* (08 September 2023).

The calcium-containing and calcium-free solution container closure systems are constructed from identical materials, with the exception of colorants used in the HF-connectors. Each bag is equipped with an HF-connector, a Luer-lock connector, and an injection port. The HF-connectors of the calcium-containing and calcium-free container closure systems contain blue and yellow colorants, respectively. The bags are composed of the materials listed in Table 2.

Table 2: Bicarby Dialysate Bag Materials

Component	Material
Solution Bag	Multi-layer Gas Barrier Film
Connective Tubing	Polyolefin/Elastomer
Injection Port	Polypropylene
	Synthetic Rubber
Luer-Lock Connector with Cap	Polycarbonate
	Thermoplastic Elastomer
HF Connector with Cap	Polycarbonate
	Silicone
Overwrap	Polyolefin/Elastomer

1.4.5. Key Performance Specifications/Characteristics

The key performance specifications of the solutions are outlined in Table 3.

Table 3: Key Performance Specifications

Chemical Component	Ionic Contribution (mEq/L, mixed)	Ionic Contribution (mEq/L, mixed)
	Calcium-containing	**Calcium-free**
Sodium (Na^+)	140	130 or 140
Potassium (K^+)	4	2 or 4
Magnesium (Mg^{2+})	1.5	1.5
Calcium (Ca^{2+})	2.5	0
Chloride (Cl^-)	113	108.5, 110.5, or 120.5
Bicarbonate ($HCO3^-$)	35	25 or 35
Glucose (g/L)	1	1

1.5. Intended Use

Bicarby Dialysate is a dialysis solution for use in acute kidney replacement therapy for the correction of blood electrolytes and acid-base balance in an extracorporeal dialysis treatment.

1.6. Indications for Use

Bicarby™ Dialysate solutions are indicated for use as a dialysis fluid for adult patients in acute care settings, requiring Kidney Replacement Therapies (KRT).

1.7. Comparison of Technological Characteristics with the Predicate Device

The proposed and predicate solutions share the same technological characteristics:

- Intended Use
- Indications for Use
- Design
- Sterilization Method
- Materials
- Principle of Operation
- Performance Specifications

The following technological characteristics of the proposed solutions are substantially equivalent to those of the predicate solutions:

- Ionic contributions (mixed) – New formulations contain different ionic contributions (mixed). Reference devices support the ionic contributions of the new formulations.
- Packaging materials – Two (2) white hot UDI stamp materials can be used with the proposed solutions. These materials were cleared through K243786 (predicate device) and K233950 (reference device).

1.8. Performance Data

The container closure system of the proposed Bicarby Dialysate solutions is identical to the predicate Bicarby and Ci-Ca Dialysate solutions (K243786). Therefore, testing was limited to chemical stability testing to evaluate the new formulations (Table 4).

Table 4: Chemical Stability Testing Summary

Testing Performed	Test Objective
Appearance	Determine the clarity and degree of opalescence of the aqueous solution
pH	Quantitatively determine the acidity or basicity of the aqueous solution
Sodium, potassium, magnesium, calcium, chloride, hydrogen carbonate, glucose, and aluminum	Quantitatively determine the concentration of sodium, potassium, magnesium, calcium, chloride, hydrogen carbonate, glucose, and aluminum in aqueous solution
5-HMF	Quantitatively determine the concentration of 5-HMF (hydroxymethylfurfural) in aqueous solution
Particulate Contamination ≥ 10 µm	Quantitatively determine the amount of extraneous, mobile undissolved particles, other than gas bubbles, unintentionally present in the aqueous solution
Particulate Contamination ≥ 25 µm	
Extractable Volume	Quantitatively determine the extractable volume of the aqueous solution
Sterility	Determine the presence of contaminating micro-organisms in the aqueous solution
Endotoxin	Quantitatively detect the presence of endotoxins from gram-negative bacteria
Loss of Weight	Determine the loss of water through the packaging material expressed as a percentage of weight loss
Dihydrogen phosphate	Quantitatively determine the concentration of phosphate in the aqueous solution
In-use Stability	Evaluate the stability of the ready-to-use solution after 48 hr

1.8.1. Biocompatibility Testing

The proposed Bicarby Dialysate solutions are packaged in the same container closure as the predicate solutions. The proposed and predicate solutions are both used for adult populations with less than 30 days use and a maximum exposure of 15 bags per day or 75 L per day (i.e., acute use environment). There is no change in patient population or environment of use.

The biocompatibility evaluations previously performed remain applicable and no new testing was performed.

1.8.2. Human Factors Validation Testing

The Bicarby Dialysate solutions were found to be safe and effective for their intended users, uses, and use environments.

1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The Bicarby Dialysate solutions are not electrical mechanical devices.

1.8.4. Software Verification and Validation Testing

Not applicable. The Bicarby Dialysate solutions do not contain software.

1.8.5. Animal Studies

No animal studies were performed.

1.8.6. Clinical Studies

No clinical studies were performed.

1.9. Conclusion

The proposed Bicarby Dialysate solutions are substantially equivalent to those of the predicate devices. Differences between the Bicarby Dialysate solutions 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, Bicarby Dialysate solutions are safe and effective for their intended use.