April 4, 2025

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

Re: K243786
Trade/Device Name: Bicarby Dialysate RFP-402 (RFP-402-G); Bicarby Dialysate RFP-400 (RFP-400-G); Bicarby Dialysate RFP-407 (RFP-407-G); Bicarby Dialysate RFP-401 (RFP-401-G); Bicarby Dialysate RFP-404 (RFP-404-G); Bicarby Dialysate RFP-456 (RFP-456-G); Ci-Ca Dialysate 2K (RFP-457-G); Ci-Ca Dialysate 4K (RFP-458-G)
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: December 9, 2024
Received: March 6, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243786

Device Name

Bicarby Dialysate RFP-402 (RFP-402-G);
Bicarby Dialysate RFP-400 (RFP-400-G);
Bicarby Dialysate RFP-407 (RFP-407-G);
Bicarby Dialysate RFP-401 (RFP-401-G);
Bicarby Dialysate RFP-404 (RFP-404-G);
Bicarby Dialysate RFP-456 (RFP-456-G);
Ci-Ca Dialysate 2K (RFP-457-G);
Ci-Ca Dialysate 4K (RFP-458-G)

Indications for Use *(Describe)*

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

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

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
Phone:	(781) 460-1087
Fax:	(781) 699-9635
Contact Person:	Timothy Groves, Senior Lead
Preparation Date:	06 December 2024

1.2. Device Name

Trade Names:	Bicarby™ Dialysate and Ci-Ca 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 and Ci-Ca solutions is the pureFLOW 400 series dialysis solutions (K233950). The pureFLOW 500 series dialysis solutions are being used as a secondary predicate device (K233159). Neither of these devices are currently subject to design-related recalls.

The B. Braun Modified Duosol Bicarbonate Dialysate (K052393) and Baxter PrismaSATE solutions (K162887) are used as reference devices.

1.4. Device Description

1.4.1. Device Identification

1.4.1.1. Bicarby and Ci-Ca Solutions

The Bicarby and Ci-Ca 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. The calcium-containing solutions are available in five (5)

formulations (Table 1), while the calcium-free solutions are available in three (3) formulations (Table 2).

Table 1: Calcium-Containing Solutions

Part Number	Description
RFP-402-G	Bicarby™ Dialysate RFP-402
RFP-400-G	Bicarby™ Dialysate RFP-400
RFP-407-G	Bicarby™ Dialysate RFP-407
RFP-401-G	Bicarby™ Dialysate RFP-401
RFP-404-G	Bicarby™ Dialysate RFP-404

Table 2: Calcium-Free Solutions

Part Number	Description
RFP-456-G	Bicarby™ Dialysate RFP-456
RFP-457-G	Ci-Ca Dialysate 2K
RFP-458-G	Ci-Ca Dialysate 4K

1.4.2. Device Characteristics

The Bicarby and Ci-Ca solutions are single-use, steam sterilized dialysis solutions for use in Kidney Replacement Therapy (KRT).

1.4.3. Environment of Use

The Bicarby and Ci-Ca solutions are used in acute care environments where KRT is performed.

1.4.4. Brief Written Description of the Device

Bicarby and Ci-Ca 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.

1.4.5. Materials of Use

The Bicarby and Ci-Ca 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 3.

Table 3: Bicarby and Ci-Ca 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

1.4.6. Key Performance Specifications/Characteristics

The key performance specifications of the solutions are outlined in Table 4.

Table 4: Key Performance Specifications

Chemical Component	Ionic Contribution (mEq/L, mixed)	Ionic Contribution (mEq/L, mixed)
	Calcium-containing	Calcium-free
Sodium (Na^+)	140	133 or 140
Potassium (K^+)	0, 2, 3, or 4	2 or 4
Magnesium (Mg^{2+})	1.0 or 1.5	1.5
Calcium (Ca^{2+})	2.5 or 3.0	0
Chloride (Cl^-)	109, 111, 112, or 113	116.5, 118.5, or 120.5
Bicarbonate ($HCO3^-$)	35	20 or 25
Glucose (g/L)	1	1

1.5. Intended Use

Bicarby and Ci-Ca solutions are dialysis solutions 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

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

Ci-Ca Dialysate

Ci-Ca 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:

- Chemical composition
- Packaging configuration
- Shelf-life
- Sterilization method
- Single use

The following technological characteristics of the proposed solutions are substantially equivalent to those of the predicate pureFLOW solutions (K233950) and secondary predicate pureFLOW solutions (K233159):

- Indications for Use and Principle of Operation – Continuous Renal Replacement Therapy (CRRT) was updated to Kidney Replacement Therapy (KRT) as these solutions can be used in other modalities in acute care settings
- Intended Use – A high-level description was added to the Intended Use to meet both U.S. and EU labeling requirements. The proposed solutions are still intended to be used as a dialysis solution/dialysate for treatment of patients with acute renal failure
- Ionic Contributions (mixed) – New formulations contain different ionic contributions (mixed). Reference devices support the ionic contributions of the new formulations.
- Packaging materials – A new white hot stamp (UDI) material was introduced. Results of biocompatibility evaluations demonstrate that the proposed bag materials are biologically safe for their intended use

These differences do not raise any different questions of safety and effectiveness.

1.8. Performance Data

The container closure system of the proposed Bicarby and Ci-Ca solutions is identical to the predicate pureFLOW (K233950) and secondary predicate pureFLOW (K233159) solutions, with the exception of the UDI stamp material. Testing conducted to support the determination of substantial equivalence is summarized in Table 5.

Table 5: Performance Testing Summary

Test Conducted	Test Method Description
Shipping and Distribution	Demonstrate the integrity and robustness of the bag system packaging within the distribution environment
HF-Connector	• Evaluate torque for removing the protective cap from the female connector and the torque of male and female connector • Evaluate breaking strength of the cone of the HF-connector • Evaluate the leakage and tightness of the connectors • Evaluate the pull-out force of the connectors and injection ports

1.8.1. Biocompatibility Testing

Biocompatibility testing was conducted to evaluate the material changes 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 assessed to support the biological safety of the Bicarby and Ci-Ca solutions container closure system:

- Chemical Characterization
- Cytotoxicity
- Sensitization
- Irritation
- Material Mediated Pyrogenicity
- Hemocompatibility
- Genotoxicity

A toxicological risk assessment was also performed.

1.8.2. Human Factors Validation Testing

The Bicarby and Ci-Ca 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 and Ci-Ca solutions are not electrical mechanical devices.

1.8.4. Software Verification and Validation Testing

Not applicable. The Bicarby and Ci-Ca 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 intended use, design, principle of operation, and performance specifications of the Bicarby and Ci-Ca solutions are substantially equivalent to those of the predicate and secondary predicate devices. Differences between the Bicarby and Ci-Ca solutions 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, Bicarby and Ci-Ca solutions are safe and effective for their intended use.