July 12, 2024

DEKA Research and Development
Paul Smolenski
Regulatory Affairs
340 Commercial Street
Manchester, NH 03101

Re: K240920
Trade/Device Name: HemoCare Bicarbonate Concentrate Set (BCS)
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: May 24, 2024
Received: May 28, 2024

Dear Paul Smolenski:

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.

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.

510(k) Number *(if known)*
K240920

Device Name
HemoCare Bicarbonate Concentrate Set (BCS)

Indications for Use *(Describe)*
The HemoCare Bicarbonate Concentrate Set (BCS) is indicated for use in the preparation of dialysate in a 3-stream proportioning hemodialysis machine with a compatible mechanical interface, such as the HemoCare Hemodialysis System. The BCS is intended for extracorporeal bicarbonate hemodialysis for chronic renal failure, 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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510(k) Summary

This 510(k) Summary of Safety and Effectiveness information is prepared in accordance with the requirements of 21 CFR Part 807.92.

1 Submitter

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Date Prepared:	July 10, 2024

2 Device

Trade Name:	HemoCare Bicarbonate Concentrate Set (BCS)
Common Name:	Sodium Bicarbonate for Hemodialysis
Classification Regulation:	21 CFR § 876.5820 - Hemodialysis system and accessories
Product Codes:	KPO
Regulatory Class:	Class II

3 Predicate Device

The Predicate Device for which Substantial Equivalence is claimed is the Gambro BiCart, cleared on January 8, 2002 under premarket notification K013724.

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4 Device Description

The HemoCare Bicarbonate Concentrate Set (BCS) is the Subject Device of this submission. It consists of powdered sodium bicarbonate in a single use cartridge with an integrated tubing assembly for interfacing with hemodialysis systems with compatible three-stream proportioning connector ports such as the HemoCare Hemodialysis System. The HemoCare System uses the bicarbonate concentrate in 3-stream, 45x proportioning to generate dialysate for bicarbonate hemodialysis therapy.

5 Indications for Use

The HemoCare Bicarbonate Concentrate Set (BCS) is indicated for use in the preparation of dialysate in a 3-stream proportioning hemodialysis machine with a compatible mechanical interface, such as the HemoCare Hemodialysis System. The BCS is intended for extracorporeal bicarbonate hemodialysis for chronic renal failure, according to a physician's prescription.

6 Substantial Equivalence Discussion

6.1 Comparison of Indications for Use

The Subject and Predicate Devices are both indicated for bicarbonate hemodialysis for chronic renal failure.

6.2 Comparison of Technical Characteristics

A summary of the technological similarities and differences between the Subject and Predicate Devices is provided in following table.

Characteristic	HemoCare BCS (Subject Device)	Gambro BiCart (Predicate Device K013724)	Comparison
Product Code	KPO	KPO	Same
Regulation Number	876.5860	876.5860	Same
Device Description	Powdered sodium bicarbonate concentrate housed in a disposable cartridge with connections for a hemodialysis system.	Powdered sodium bicarbonate concentrate housed in a disposable cartridge with connections for a hemodialysis system.	Same
Intended Use	Bicarbonate concentrate intended for use in bicarbonate hemodialysis.	Bicarbonate concentrate intended for use in bicarbonate hemodialysis.	Same

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Characteristic	HemoCare BCS (Subject Device)	Gambro BiCart (Predicate Device K013724)	Comparison
Indications for Use	The HemoCare Bicarbonate Concentrate Set (BCS) is indicated for use in the preparation of dialysate in a 3-stream proportioning hemodialysis machine with a compatible mechanical interface, such as the HemoCare Hemodialysis System. The BCS is intended for extracorporeal bicarbonate hemodialysis for chronic renal failure, according to a physician's prescription.	Gambro BiCart is intended for use in a bicarbonate hemodialysis for acute and chronic renal failure, or acute intoxication with dialyzable substances.	Substantially Equivalent. Both devices supply powdered sodium bicarbonate concentrate for use in hemodialysis systems having 3-stream, 45x dialysate proportioning
Prescription Use	Yes	Yes	Same
Single Use	Yes	Yes	Same
Use-life	2 years	2 years	Same
Disposable	Yes	Yes	Same
Dialysate Proportioning	three stream proportioning	three stream proportioning	Same
Acid Dilution Ratio	1:44 (45x)	1:44 (45x)	Same
Sodium Bicarbonate Grade	USP grade dry sodium bicarbonate powder	USP grade dry sodium bicarbonate powder	Same
Bicarbonate powder quantity	720 g	650 g, 720 g and 1150 g	Substantially Equivalent
Storage Temperature	Store 15°C to 30°C	Store below 40 °C	Substantially Equivalent
Housing material	Polypropylene	Polypropylene	Same

7 Performance Data

The following performance data were provided to support the substantial equivalence determination:

Biocompatibility Testing

Biocompatibility testing was performed in accordance with ISO 10993-1:2018 and FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (2023). The following endpoints were evaluated to support the biological safety of the HemoCare BCS:

- Cytotoxicity
- Sensitization

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- Irritation
- Acute Systemic Toxicity
- Subacute System Toxicity
- Pyrogenicity
- Genotoxicity
- Hemocompatibility

Bench Performance Testing

Benchtop verification testing was performed to verify specified performance across the following areas:

- Dialysate Quality
- Microbial Safety
- Distribution, Storage and Shelf Life

8 Conclusion

The results of non-clinical testing demonstrate that the HemoCare Bicarbonate Concentrate Set meets all performance specifications and is safe and effective. The minor differences between the HemoCare Bicarbonate Concentrate Set and the predicate device do not raise any new or different questions of safety or effectiveness. The HemoCare Bicarbonate Concentrate Set is substantially equivalent to the predicate device.