March 3, 2023

Renal Care Dialysis Solutions, S.A. DE C.V.
% Brittany Valdez Nava
Head of Quality
Healthcare Innovations Catalysts
7811 Montrose Road, Suite 215
Potomac, Maryland 20854

Re: K221652
Trade/Device Name: Nikkicart
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KPO
Dated: January 30, 2023
Received: February 1, 2023

Dear Brittany Valdez Nava:

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,

Gema Gonzalez -S

Gema Gonzalez, MS
Acting 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)*
K221652

Device Name
NIKKICART

Indications for Use *(Describe)*
The NikkiCart cartridge is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute renal failure, chronic renal failure, or acute intoxication with dialyzable substances. The NikkiCart cartridge is intended to be used as one component in the preparation of dialysate according to a physician's prescription in a 3-stream proportioning machine on the Nikkiso DBB-06 dialysis system equipped with a compatible bicarbonate cartridge holder.

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.

1 510(k) Summary

a. Company Name, Address:
RENAL CARE DIALYSIS SOLUTIONS, S.A. DE C.V.
Carretera a los Cues K.M. 2.2., Lote 23, Bodegas 5 y 6, Parque Tecnològico Innovaciòn Querètaro
El Marquès, Querètaro 76246
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b. Contact:
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c. Official Correspondent:
Brittany Valdez Nava
Head of Quality
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7811 Montrose Road, Suite 215
Potomac, Maryland 20854

d. Date prepared
June 6, 2022

e. Date revised
January 26, 2023

f. Subject Device

Device Name:	NikkiCart
Device Classification Name:	Hemodialysis system and accessories
Regulation Number:	21 CFR 876.5820
Common Name:	Sodium Bicarbonate for Hemodialysis
Device Class:	Class II
Classification Product Code:	KPO
Regulation Medical Specialty:	Gastroenterology/Urology
510(k) Review Panel:	Gastroenterology/Urology

g. Predicate Device

The NikkiCart cartridge is substantially equivalent to:

510(k) Number:	K013724
Device Name:	Gambro BiCart®
Applicant:	GAMBRO Renal Products
Device Classification Name:	Dialysate Concentrate For Hemodialysis (Liquid Or Powder)
Regulation Number:	21 CFR 876.5820
Common Name:	Sodium Bicarbonate for Hemodialysis
Device Class:	Class II
Classification Product Code:	KPO
Regulation Medical Specialty:	Gastroenterology/Urology
510(k) Review Panel:	Gastroenterology/Urology

h. Device Description

The NikkiCart is a single use polypropylene (PP) cartridge containing dry sodium bicarbonate powder, which enables on-line preparation of saturated Sodium Bicarbonate solution that, in conjunction with appropriate acid concentrate solution and dialysis water, creates a bicarbonate -based dialysis fluid that meets the Association for the Advancement of Medical Instrumentation (AAMI) guidelines.

When the NikkiCart is attached to the Nikkiso DBB-06 dialysis machine with a compatible bicarbonate cartridge holder, water is drawn by the dialysis machine through the cartridge, producing a saturated solution of sodium bicarbonate. The dialysis machine mixes the sodium bicarbonate solution with water and the acid concentrate to produce a bicarbonate-based dialysis fluid. The acid concentrate must have a dilution ratio of 1:44 also known as 45X to be used with the NikkiCart Sodium Bicarbonate cartridge.

i. Intended Use

The NikkiCart cartridge is intended for preparation of hemodialysis solutions on theNikkiso dialysis systems. The NikkiCart must always be used with a suitable acid concentrate.

Indications for Use

The NikkiCart cartridge is indicated for use in patients undergoing extracorporeal bicarbonate hemodialysis for acute renal failure, chronic renal failure, or acute intoxication with dialyzable substances. The NikkiCart cartridge is intended to be used as one component in the preparation of dialysate according to a physician's prescription in a 3-stream proportioning machine on the Nikkiso DBB-06 dialysis system equipped with a compatible bicarbonate cartridge holder.

j. Statement of Substantial Equivalence

The NikkiCart is substantially equivalent to the predicate GAMBRO BiCart® (K013724) regarding the following:

- Indications for use
- Technological characteristics

- Chemical composition
- Materials of construction

Table 1 below present a comparison of the NikkiCart cartridge to the predicate BiCart (K013724) cartridge. The only functional difference between BiCart and the NikkiCart is the quantity of sodium bicarbonate contained in each cartridge. The different quantities of sodium bicarbonate provide for different lengths of treatment; the resulting saturated sodium bicarbonate solution is used in the same way.

k. Comparison Table

Table 1: Comparison table between BiCart (K013724) and the NikkiCart

	Predicate Device: BiCart (K013724)	Proposed Device: NikkiCart	Discussion
Fill Weight	720g and 1250g	720g and 900g	Substantially Equivalent
Dimensional/Geometrical Measurements	Total Height – 236.01mm BODY Nipple Height – 10.27 mm BODY Nipple Diameter – 9.90mm CAP Nipple Height – 10.30mm CAP Nipple Diameter – 9.89mm	Total Height → 235.26mm BODY Nipple Height → 10.04mm BODY Nipple Diameter →9.98mm CAP Nipple Height → 10.02mm Cap Nipple Diameter → 9.82mm	Substantially Equivalent
Machine Interface Dimensions	No data available	Lower Arm O-ring(interface with nipple): • Distance: 8.52mm • Diameter: 9.49mm Upper Arm O-ring (interface with nipple): • Distance to bottom – O-ring: 4.37mm • Diameter 1 (interface with nipple): 9.48mm • Distance: 10.06mm Diameter 2 (Seal Upper /Lower area when closed): 16.19mm	
Duration of Use	720g: • 500ml/min dialysis flow rate: 6h 45min • 700ml/min dialysis flow rate: 4h 50 min 1250g: • 500ml/min dialysis flow rate: 12h 26min • 600ml/min dialysis flow rate: 10h 22min • 700ml/min dialysis flow rate: 8 h 53 min	720g: • 500ml/min dialysis flow rate: 6h 45min • 600ml/min dialysis flow rate: 5h 37 min 900g: • 500ml/min dialysis flow rate: 8h 41min • 800ml/min dialysis flow rate: 5h 25min	Substantially Equivalent
Acid Dilution Ratio	1:44	1:44	Identical

Final Dialysate Conductivity	Final dialysate Conductivity 13.7mS/cm with Centrisol Acid concentrate SB-111.	Final dialysate Conductivity 13.7mS/cm with Centrisol Acid concentrate SB-111	Identical
Fill Water Temperature	33.0°C to 40.0°C	34.0°C to 40.0°C	Substantially Equivalent
Compatible Hemodialysis Models	Baxter Phoenix and AK98 hemodialysis models	Nikkiso DBB-06 hemodialysis model	
The variation in the sizes offered does not raise any questions of the safety and effectiveness of our device because these sizes will accommodate the Nephrologist prescription for the patient's hemodialysis treatment, e.g., Treatment time dialysate flow rate and Sodium Bicarbonate.			
Indications for Use	To be used in bicarbonate hemodialysis treatment for patients suffering from acute renal failure, chronic renal failure, or acute intoxication with dialyzable substances.	To be used in a bicarbonate dialysis treatment for patients suffering from acuterenal failure, chronic renal failure, or acute intoxicationwith dialyzable substances.	Identical
Disposable	Yes	Yes	Identical
Sodium Bicarbonate Grade	USP & European Pharmacopeia	USP & European Pharmacopeia	Identical
Bicarbonate Concentration	38 mEq/L	37 mEq/L	Substantially Equivalent
The difference in the bicarbonate concentration does not raise new issues of safety and effectiveness because the dialysis machine Sodium Bicarbonate is prescribed by the Nephrologist to be specific to the patient medical status.			
Storage Condition	Store below +40 °C (+104 °F)	Store below +30 °C (+86 °F)	Substantially Equivalent
The difference in storage conditions does not raise new issues of safety and effectiveness because the bench testing data showed that bicarbonates integrity was not compromised.			
Housing Material	Polypropylene	Polypropylene	Identical

l. Performance Data

The proposed device has been subjected to biocompatibility testing, functional performance testing, and stability testing to support safety and effectiveness. No clinical testing was performed.

The following endpoints were assessed to support the biological safety of the NikkiCart

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity
- Material mediated pyrogenicity
- Hemocompatibility

Stability evaluations were conducted for the NikkiCart in support of the 24-month (2-year) shelf life. The 24-month shelf life is supported by real time stability evaluations.

Additionally, a chemical characterization assessment was conducted to assess the following endpoints to support the biological safety of the NikkiCart:

- Chronic systemic toxicity
- Mutagenicity/Carcinogenicity

Shipping and distribution verification testing was performed for the NikkiCart in accordance with ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems. Results support that the product's packaging can withstand the distribution environment.

There are no differences between the predicate device (K013724) and the proposed device that raise new issues of safety and effectiveness.

m. Conclusion

The intended use, technological characteristics, chemical composition, and materials of construction of the NikkiCart sodium bicarbonate cartridge are substantially equivalent to the BiCart (K013724) bicarbonate cartridge the predicate device. The non-clinical data support the safety of the NikkiCart and demonstrate the device performs as intended. Differences between the NikkiCart Bicarbonate cartridge and the predicate do not raise new or modified issues of safety or efficacy.