September 14, 2023

Baxter Healthcare Corporation
Kristen Bozzelli
Senior Manager, Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, Illinois 60073

Re: K232467
Trade/Device Name: CleanCart A, CleanCart C, AK 98 Dialysis Machine
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Received: August 15, 2023

Dear Kristen Bozzelli:

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
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)*
K232467

Device Name
CleanCart A, CleanCart C and AK 98 Dialysis Machine

Indications for Use *(Describe)*
The CleanCart A cartridge is intended for preparation of a sodium carbonate solution used for removing organic deposits, fats and proteins from the dialysis machine's fluid circuit.

The CleanCart A cartridge must be used in combination with the heat disinfection program of the corresponding dialysis machine.

The CleanCart C cartridge is intended for preparation of a citric acid solution used for removing calcium and magnesium precipitation from the dialysis machine's fluid circuit.

The CleanCart C cartridge must be used in combination with the heat disinfection program of the corresponding dialysis machine

The Baxter AK 98 Dialysis machine is intended to be used for intermittent hemodialysis and/or isolated ultrafiltration treatments of patients with chronic or acute renal failure or fluid overload upon prescription by a physician. The AK 98 Dialysis Machine is indicated to be used on patients with a body weight of 25 kg or more. The AK 98 Dialysis Machine is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis or hospital care environment. The Baxter AK 98 Dialysis Machine is not intended for Selfcare or home use.

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.

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Section 5. 510(k) Summary

15 August 2023

OWNER:

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IDENTIFICATION OF THE DEVICE:

Common Name: Hemodialysis Delivery System
Trade/Device Name: CleanCart A, CleanCart C, AK 98 Dialysis Machine

Classification Panel: Gastroenterology/Urology
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI

Table 1. Device Configurations

Device Description	Code Number
CleanCart A Cartridge (Sodium Carbonate)	955850
CleanCart C Cartridge (Citric Acid)	955851
AK 98 Dialysis Machine	955607

PREDICATE DEVICE:

This Special 510(k) is being submitted to add CleanCart A and CleanCart C as accessories of the AK 98 Machine. CleanCart A and CleanCart C were previously cleared for use with the Phoenix Dialysis System.

Table 2. Predicate Device(s)

Device	Predicate 510(k)	Clearance Date
CleanCart A Cartridge (Sodium Carbonate)	K001156	7 July 2000
CleanCart C Cartridge (Citric Acid)	K001156	7 July 2000
AK 98 Dialysis Machine	K201809	10 March 2021

DESCRIPTION OF THE DEVICE:

CleanCart A and Cleancart C products are accessories for the maintenance of the dialysis fluid pathway of hemodialysis machines equipped with a compatible cartridge holder. CleanCart products are compatible with the BiCart holder of the AK 98 Dialysis Machine (K201809). The AK 98 Dialysis Machine and CleanCart products will be used in chronic care dialysis or hospital care environments. The CleanCart products are used in combination with a heat disinfection cycle; the patient is not connected with the hemodialysis machine during this process.

The CleanCart A cartridge contains 13 grams of anhydrous sodium carbonate powder. The CleanCart A cartridge is intended for the preparation of a sodium carbonate solution used for removing organic deposits, fats and proteins from the dialysis machine's fluid circuit. The diluted solution has a pH of approximately 11.

The CleanCart C cartridge contains 32 grams of citric acid anhydrous powder. The CleanCart C cartridge is intended for preparation of a citric acid solution used for removing calcium and magnesium precipitation from the dialysis machine's fluid circuit. The diluted solution has a pH of approximately 2.

INDICATIONS FOR USE:

The CleanCart A cartridge is intended for preparation of a sodium carbonate solution used for removing organic deposits, fats and proteins from the dialysis machine's fluid circuit. The CleanCart A cartridge must be used in combination with the heat disinfection program of the corresponding dialysis machine.

The CleanCart C cartridge is intended for preparation of a citric acid solution used for removing calcium and magnesium precipitation from the dialysis machine's fluid circuit.

The CleanCart C cartridge must be used in combination with the heat disinfection program of the corresponding dialysis machine.

And

The Baxter AK 98 dialysis machine is intended to be used for intermittent haemodialysis and/or isolated ultrafiltration treatments of patients with chronic or acute renal failure or fluid overload upon prescription by a physician.

The AK 98 dialysis machine is indicated to be used on patients with a body weight of 25 kg or more. The AK 98 dialysis machine is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis or hospital care environment. The Baxter AK 98 dialysis machine is not intended for Selfcare or Home use.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

No design changes were required for CleanCart products to be compatible for use with the AK 98 Dialysis Machine. The technological characteristics are described in the device comparison tables below.

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Table 3. Device Comparison CleanCart A

Features	Predicate Device CleanCart A Cleared under K001156	Proposed Device CleanCart A (955850)	Assessment of Differences
Intended Use/ Indications for Use	The CleanCart A product is intended for preparation of a sodium carbonate solution used for removing organic deposits, fats, and proteins from the dialysis machine's fluid circuit. The CleanCart A product must be in combination with the heat disinfection program of the corresponding dialysis machine	The CleanCart A cartridge is intended for preparation of a sodium carbonate solution used for removing organic deposits, fats and proteins from the dialysis machine's fluid circuit. The CleanCart A cartridge must be used in combination with the heat disinfection program of the corresponding dialysis machine.	No significant difference.
Sterile	No	Same	N/A
Non-Pyrogenic	No	Same	N/A
Single Use	Yes	Same	N/A
Electromechanical device compatibility	Compatible with Phoenix	Add Compatibility to AK 98	The AK and Phoenix machines incorporate the BiCart holder, which is compatible with the CleanCart products. The CleanCart products perform the same function on both devices.
Materials	Neither directly nor indirectly patient contacting	Same	N/A
Sodium Carbonate powder	anhydrous sodium carbonate powder	Same	N/A
Tube	Polypropylene tube	Same	N/A
Cap	Polypropylene	Phthalate-free polypropylene	No significant difference

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Table 3. Device Comparison CleanCart A

Features	Predicate Device CleanCart A Cleared under K001156	Proposed Device CleanCart A (955850)	Assessment of Differences
	PET Net filter	Same	N/A
Length	235mm	238.3mm	No significant difference
Shelf life	2 years	Same	N/A

Table 4. Device Comparison CleanCart C

Features	Predicate Device CleanCart C Cleared under K001156	Proposed Device CleanCart C (955851)	Assessment of Differences
Intended Use/ Indications for Use	The CleanCart C product is intended for preparation of a citric acid solution used for removing calcium and magnesium precipitation from the dialysis machine's fluid circuit. The CleanCart C product used in combination with the heat disinfection program increases the efficiency of the disinfection program	The CleanCart C cartridge is intended for preparation of a citric acid solution used for removing calcium and magnesium precipitation from the dialysis machine's fluid circuit. The CleanCart cartridge must be used in combination with the heat disinfection program of the corresponding dialysis machine	No significant difference
Sterile	No	Same	N/A
Non-Pyrogenic	No	Same	N/A

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Table 4. Device Comparison CleanCart C

Features	Predicate Device CleanCart C Cleared under K001156	Proposed Device CleanCart C (955851)	Assessment of Differences
Single Use	Yes	Same	N/A
Electromechanical device compatibility	Compatible with Phoenix Dialysis machine	Compatible with AK 98 Dialysis machine	The AK and Phoenix machines incorporate the BiCart holder, which is compatible with the CleanCart products. The CleanCart products perform the same function on both devices
Materials	Neither directly nor indirectly patient-contacting	Same	N/A
Citrate	Anhydrous citric acid powder	Same	N/A
Tube	Polypropylene	Same	N/A.
Cap	Polypropylene	Phthalate free Polypropylene	No significant difference
Cap	PET Net Filters	Same	N/A
Length	235mm	238.3mm	No significant difference
Shelf Life	2 years	Same	N/A

Table 5. Device Comparison AK 98 Dialysis Machine

Features	Predicate Device AK 98 Cleared under K201809	Proposed Device AK 98	Assessment of Differences
Intended use	The Baxter AK 98 dialysis machine is intended to be used for intermittent haemodialysis and/or isolated	Same	N/A

Table 5. Device Comparison AK 98 Dialysis Machine

Features	Predicate Device AK 98 Cleared under K201809	Proposed Device AK 98	Assessment of Differences
	ultrafiltration treatments of patients with chronic or acute renal failure or fluid overload upon prescription by a physician. The AK 98 dialysis machine is indicated to be used on patients with a body weight of 25 kg or more. The AK 98 dialysis machine is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis or hospital care environment. The Baxter AK 98 dialysis machine is not intended for Selfcare or Home use.		
Treatment modalities	**Hemodialysis** - HD DN/SP treatment - HD SN/SP treatment	Same	N/A
Dialysate conductivity monitoring	Yes	Same	N/A
Isolated UF	Yes	Same	N/A
Ultrafiltration control	Yes	Same	N/A
Ultrafiltration supervision	Yes, supervision in accordance with IEC 60601-2-16, 4th edition	Same	N/A
Ultrafiltration accuracy	Between ±50 and ±100 g/h, depending on ultrafiltration rate.	Same	N/A

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Table 5. Device Comparison AK 98 Dialysis Machine

Features	Predicate Device AK 98 Cleared under K201809	Proposed Device AK 98	Assessment of Differences
	Note: Ultrafiltration accuracy calculated per section 13.1.6 in the AK 98 Operator's Manual Ultrafiltration control:		
Air detector	Yes	Same	N/A
Blood leak detector	Yes	Same	N/A
Temperature monitoring	Yes	Same	N/A
Fail-safe response during power failure	Yes	Same	N/A
Prescription profiling	Conductivity profiling (Na, HCO_3)	Same	N/A
Disinfection programs	Heat Chemical	Same with the addition of instructions to use the Heat and CleanCart disinfection cycles. These cycles use heat to disinfect the fluid path, and also use a CleanCart Cartridge to remove organic deposits or descale the fluid path.	The Heat and CleanCart Cycles are included in the cleared software and were verified and validated in the same process. Design reviews were performed to assure that these cycles are covered by previously performed microbial disinfection and human factors testing.
Anti coagulant administration rate:	0 – 10.0 ml/h	Same	N/A
Anti coagulant bolus:	0 – 10.0 ml	Same	N/A
Blood Flow Rate	20 -600 ml/min	Same	N/A
Blood flow rate accuracy	For pre-pump pressure range from -200 mmHg to 0 mmHg:	Same	N/A

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Table 5. Device Comparison AK 98 Dialysis Machine

Features	Predicate Device AK 98 Cleared under K201809	Proposed Device AK 98	Assessment of Differences
	±10 mL/min or ±10% of the set point value, whichever is the largest		
Dialysate Flow Rate	300 – 800 ml/min	Same	N/A
Dialysate Flow Rate accuracy	±10 % or 50 mL/min whichever is largest	Same	N/A
Transmembrane Pressure (TMP)	-200 - +500 mmHg (calculated value) set of LIMITS	Same	N/A
Net Fluid Removal Rate	0 – 4 L /h	Same	N/A
Dialysate Temperature	33 – 40 °C	Same	N/A
Dialysate Conductivity set range	9-16 mS/cm	Same	N/A
Arterial pressure	-400 - +300 mmHg	Same	N/A
Venous Pressure	+10 – +500 mmHg	Same	N/A
Blood pressure measurements (BPM)	Yes	Same	N/A
IT connectivity	Yes – Integrates with CIS (clinical information system) using HL7 protocol	Same	N/A

DISCUSSION OF NONCLINICAL TESTS:

No design changes were required for CleanCart products to be compatible for use with the AK 98 Dialysis Machine, therefore no additional testing has been performed in support of this change. The data demonstrating that CleanCart and AK 98 products can be used together was part of the AK 98 510(k) submission (K201809). Design reviews were performed to determine if the microbiological disinfection verification and human factors studies submitted in K201809 were relevant to the use of CleanCart products and AK 98. Both reviews determined use of the Heat and CleanCart cycles was covered by existing data, and no additional testing was needed.

Biocompatibility:

No biocompatibility data is required in support of this submission.

The CleanCart products clean the fluid path of the AK 98 machine and are rinsed away during disinfection cycles. As such, the CleanCart products are not present during dialysis treatments; they neither directly nor indirectly contact the patient.

There are no material changes to the AK 98 Dialysis Machine; the biocompatibility data supporting this product is not changed.

CONCLUSION:

Design reviews of previously submitted data support that the use of CleanCart A and CleanCart C with the AK 98 Dialysis Machine is substantially equivalent to the use of CleanCart A and CleanCart C with the Phoenix Dialysis machine.