DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 6, 2017

Baxter Healthcare Corporation
Kristen Bozzelli
Manager, Regulatory Affairs
32650 North Wilson Road
Round Lake, IL 60073

Re: K162887
Trade/Device Name: PrismaSATE dialysis solutions
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: KPO
Dated: December 8, 2016
Received: December 12, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
TBD K162887

Device Name
PrismaSATE dialysis solutions

Indications for Use *(Describe)*
PrismaSATE solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.

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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Section 5. 510(k) Summary

January 5, 2017

OWNER:

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IDENTIFICATION OF THE DEVICE:

Common Name: Dialysate Solutions for Continuous Renal Replacement Therapy (CRRT) Ready to Use Sterile Dialysate.
Trade Name or Proprietary Name: PrismaSATE
Classification Panel: Gastroenterology/Urology
Classification: 21 CFR 876.5820 Dialysate concentrate for hemodialysis (liquid or powder)
Class: Class II
Product Code: KPO

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PREDICATE DEVICE:

The predicate devices are the PrismaSATE dialysis solution formulations buffered by bicarbonate using hydrochloric acid as an excipient (pH adjustor) in PVC packaging cleared under K120333, and PrismaSATE dialysis solutions buffered by bicarbonate with lactate in polyolefin primary packaging cleared under K072908.

Table 1. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
PrismaSATE dialysate solutions, bicarbonate buffered with HCl excipient in PVC packaging	Baxter Healthcare (formerly Gambro Renal Products, Inc.)	K120333	May 31, 2012
PrismaSate dialysate solutions bicarbonate buffered with lactate in polyolefin packaging	Baxter Healthcare (formerly Gambro Renal Products, Inc.)	K072908	February 2, 2008

DESCRIPTION OF THE DEVICE:

PrismaSATE dialysis solutions are ready to use sterile dialysate solutions for use in Continuous Renal Replacement Therapy (CRRT) for the treatment of acute renal failure and in other cases necessitating fluid or solute removal, such as in the case of drug poisoning with dialyzable or filterable substances. The solutions are intended to be used with commercially available CRRT systems as dialysate. A physician prescribes the chemical composition of the solution to be used. The solutions are sterile, and packaged in flexible bags. The composition of the fluid used in renal therapies mirrors normal plasma water, since normalization of the blood is the objective.

PrismaSATE solutions, like other currently available dialysate solutions, consist of various quantities of the following chemicals: sodium chloride, potassium chloride, magnesium chloride, calcium chloride, dextrose, and a buffer of lactose and/or bicarbonate. The solution is prescribed by a physician; the physician selects the appropriate formulation based on the patient's blood electrolyte level and desired traits. PrismaSATE dialysate solutions are offered in a range of electrolyte concentrations which mirror the range of electrolytes in plasma. The solution may be buffered using lactate, bicarbonate using lactic acid as a pH adjustor, or bicarbonate using hydrochloric

acid as a pH-adjusting excipient.. No changes to the available solution formulations are described in this Special 510(k).

The bicarbonate buffered PrismaSATE solutions currently on the market may be packaged in Polyvinyl Chloride (PVC) or in Polyolefin (non-PVC) two compartment bags. The final solution is obtained by breaking a frangible (PVC) or peel seal (non-PVC) between the compartments and mixing both solutions just prior to use. Neither the bag design nor the bag materials are being changed; they are not the subject of this Special 510(k).

The purpose of this Special 510(k) is to expand the PrismaSATE solution formulations buffered with bicarbonate using hydrochloric acid as a pH-adjusting excipient into the polyolefin primary packaging materials. The formulations that are the subject of this submission are described in the Table 2 below.

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Table 2. PrismaSATE dialysate solution bicarbonate buffered with HCl excipient, packaged in polyolefin

Composition for small compartment (contains 250 ml)			
Formulation	**Calcium Chloride**	**Magnesium Chloride**	**Water for Injection**
BzK 2/0	-	2.44	q.s.
BzK 4/2.5	3.68	3.05	q.s.
BzK 0/3.5	5.15	2.03	q.s.

Composition for large compartment (contains 4750 ml)				
Formulation	**Sodium Chloride**	**Potassium Chloride**	**Sodium Bicarbonate**	**Water for Injection**
BzK 2/0	6.46	0.157	3.09	q.s.
BzK 4/2.5	6.46	0.314	3.09	q.s.
BzK 0/3.5	6.46	-	3.09	q.s.

Composition after reconstitution in mmol/l						
Formulation	**Na^+**	**K^+**	**Ca^{2+}**	**Mg^{2+}**	**HCO_3^-**	**Cl^-**
BzK 2/0	140	2	0	0.6	32	111.2
BzK 4/2.5	140	4	1.25	0.75	32	116.0
BzK 0/3.5	140	0	1.75	0.5	32	112.5

Composition after reconstitution in mEq/l						
Formulation	**Na^+**	**K^+**	**Ca^{2+}**	**Mg^{2+}**	**HCO_3^-**	**Cl^-**
BzK 2/0	140	2	0	1.2	32	111.2
BzK 4/2.5	140	4	2.5	1.5	32	116.0
BzK 0/3.5	140	0	3.5	1.0	32	112.5

INDICATIONS FOR USE:

PrismaSATE solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed device has the same technological characteristics as the predicate device.

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Table 3. Device Comparison Table

Features	Predicate Device PrismaSATE K120333	Predicate Device PrismaSATE K072908	Proposed Device
Indications for use	Gambro PrismaSATE Solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy	Gambro PrismaSATE Solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy	Same: PrismaSATE Solutions are indicated for use as a dialysate in Continuous Renal Replacement Therapy.
Sterile	Steam sterilized, to a Sterilization Assurance Level of at least 10-6.	Steam sterilized, to a Sterilization Assurance Level of at least 10-6.	Same: Steam sterilized, to a Sterilization Assurance Level of at least 10-6.
Non-Pyrogenic	Non-pyrogenic solution	Non-pyrogenic solution	Same: Non-pyrogenic solution
Single Use	Yes	Yes	Same: Yes
Solution Formulation	PrismaSATE solution formulations buffered with bicarbonate using hydrochloric acid as excipient	PrismaSATE solutions buffered with bicarbonate with lactate	Same as predicate K120333
Primary Packaging material	PVC	Polyolefin	Same as predicate K072908 : Polyolefin
Shelf life	12 months	18 months	Same as predicate K072908: 18 months

DISCUSSION OF NONCLINICAL TESTS:

A risk analysis was performed on the proposed combination of PrismaSATE solution formulations buffered with bicarbonate using hydrochloric acid as a pH-adjusting excipient (cleared under K120333) in the polyolefin primary packaging materials (cleared under K072908). No new risks were identified.

Baxter Healthcare Corporation performed design verification for the modification. The result met its acceptance criteria, and supports that the proposed device is appropriately designed for its intended use.

Performance Data:

No performance data is included in this Special 510(k).

Biocompatibility:

No new materials are introduced in this Special 510(k). No biocompatibility data is necessary.

CONCLUSION:

The design control activities demonstrate that the subject device is substantially equivalent and performs comparably to the predicate device.