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

May 3, 2017

Baxter Healthcare Corporation
Chris Scavotto
Senior Manager Regulatory Affairs
32650 N. Wilson Road
Round Lake, IL 60073

Re: K163530
Trade/Device Name: PrisMax
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: March 31, 2017
Received: April 4, 2017

Dear Chris Scavotto:

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,

Joyce M. Whang -S

for

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)*

K163530

Device Name
PrisMax

Indications for Use *(Describe)*

The PrisMax control unit is intended for:

• Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload.

All treatments administered via the PrisMax control unit must be prescribed by a physician.

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

December 15th, 2016

OWNER:

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IDENTIFICATION OF THE DEVICE:

Common Name: Hemodialysis Delivery System
Trade Name or Proprietary Name: PrisMax
Classification Panel: 78 Gastroenterology and Urology
Classification: High Permeability Hemodialysis System (876.5860)
Class: Class II
Product Code: 78KDI

Table 1. Product Code(s) for PrisMax System

Code Number	Name
115369	PrisMax control unit
115370	PrisMax Accessory, Auto Effluent
115485	PrisMax Accessory, Auto Effluent Extension

PREDICATE DEVICE:

Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
Prismaflex	Gambro Lundia AB	K131516	1/3/2014

DESCRIPTION OF THE DEVICE:

The PrisMax System is intended for Continuous Renal Replacement Therapy (CRRT) for patients with acute renal failure and/or fluid overload. Reference the PrisMax control unit in Figure 1.

The goals of acute renal failure treatments are removal of waste products, restoration of acid-base balance; correction of electrolyte imbalances (e.g., hyperkalemia), patient fluid balance, nutritional support, and other conditions in which fluid removal is needed. PrisMax System offers four Continuous Renal Replacement Therapy (CRRT) options: Slow Continuous Ultrafiltration (SCUF), Continuous Veno-Venous Hemofiltration (CVVH), Continuous VenoVenous Hemodialysis (CVVHD), and Continuous Veno-venous Hemodialfiltration (CVVHDF).

Figure 1. PrisMax control unit

The proposed device PrisMax, which is the subject of this Traditional 510(k) premarket notification, consists of PrisMax Control Unit. Also included are accessories for removing effluent. The proposed device PrisMax uses the current marketed device

Prismaflex as the predicate. The Prismaflex was previously cleared under 510(k) premarket notification K131516 (cleared on January 3rd, 2014).

INDICATIONS FOR USE:

The PrisMax control unit is intended for:

- Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload.

All treatments administered via the PrisMax control unit must be prescribed by a physician.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The differences between the predicate Prismaflex 7.10 and the proposed device PrisMax as reflected in the Substantial Equivalence (SE) Table are considered substantially equivalent. Changes included in the SE table are marked and discussed in Table 3.

Identification of Predicate Device:

- Trade Name: Prismaflex, 7.10
- Manufacturer: Gambro Lundia AB, Sweden
- Common Name: Hemodialysis Delivery System.
- Clearance: K0131516 cleared in January 2014.

Identification of Proposed Device:

- Trade Name: PrisMax, 1.0.6.0.
- Manufacturer: Gambro UF Solutions, Minneapolis Minnesota
- Common Name: Hemodialysis Delivery System.
- Clearance: Pending.

PrisMax will not utilize the TPE2000 Blood Tubing Set. It will utilize the CRRT Blood Tubing sets referenced in the Substantial Equivalence Table (M60/M100/M150 + HF1000/HF1400) all which have been previously cleared. The predicate device Prismaflex was cleared in 2011 to include TPE2000 Blood Sets. The PrisMax is not

requesting clearance for TPE Blood Sets. References to TPE have been removed from Table 3.

Table 3. Substantial Equivalence Table Device Comparison

Features	SE	Proposed PrisMax 1.0.6.0	Predicate Prismaflex 7.10, K131516
Indications for use	SE	The PrisMax control unit is intended for: • Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload. All treatments administered via the PrisMax control unit must be prescribed by a physician.	The Prismaflex control unit is intended for: • Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload. All treatments administered via the Prismaflex control unit must be prescribed by a physician.
Dedicated Disposable Sets Available in U.S.	SE	For CRRT: M60/M100/M150 HF1000 & HF1400	For CRRT: M60/M100/M150 HF1000 & HF1400
Syringe Sizes [A]	SE	20 & 50 ml	20, 30 & 50 ml
Anticoagulation	SE	User-controllable as continuous or bolus	User-controllable as continuous or bolus
Dialysate Flow Rate [B]	SE	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 10 ml/hr	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 50 ml/hr
Dialysate Flow Rate Accuracy	SE	± 30 ml/hr	± 30 ml/hr
Replacement solution / Fluid Flow Rate [C]	SE	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 10 ml/hr	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 50 ml/hr
Replacement Flow Rate Accuracy	SE	± 30 ml/hr	± 30 ml/hr
Blood Flow Rate	SE	Range: 10-450 ml/min	Range: 10-450 ml/min
Blood Flow Rate Accuracy	SE	±10 % of user-set rate at nominal blood flow of 450 ml/min or the highest achievable disposable blood flow, having 37 ºC, at an access pressure of -200 mmHg and without any PBP flow	±10 % of user-set rate at nominal blood flow of 450 ml/min or the highest achievable disposable blood flow, having 37 ºC, at an access pressure of -200 mmHg and without any PBP flow

Table 3. Substantial Equivalence Table Device Comparison

Features	SE	Proposed PrisMax 1.0.6.0	Predicate Prismaflex 7.10, K131516
Pre-Blood Pump Flow Rate [D]	SE	SCUF: Range: 0 to 2000 ml/hr CVVH, CVVHD, CVVHDF: Range: 0 to 4000 ml/hr	SCUF: Range: 0 to 1000 ml/hr CVVH, CVVHD, CVVHDF: Range: 0 to 4000 ml/hr
Pre-Blood Pump Accuracy	SE	± 30 ml/hr	± 30 ml/hr
Effluent Pump Flow Rate	SE	Range: 0 to 10,000 ml/h Depending on the therapy selected.	Range: 0 to 10,000 ml/h Depending on the therapy selected.
ECG Discharger	SE	YES	YES
Therapies	SE	SCUF CVVH CVVHD CVVHDF	SCUF CVVH CVVHD CVVHDF
Pumps	SE	PBP solution Replacement solution Dialysate solution Effluent Blood	PBP solution Replacement solution Dialysate solution Effluent Blood
Scales	SE	Dialysate Replacement Effluent Pre blood (PBP)	Dialysate Replacement Effluent Pre blood (PBP)
Trans Membrane Pressure Alarms TMP (CRRT) [E]	SE	CRRT TMP: Default: +300 mmHg	CRRT TMP: User settable: +70 to +350 mmHg Default: +350 mmHg
Dialysate Conductivity and Temperature	SE	Dialysate Conductivity and Temperature are not controlled by PrisMax	Dialysate Conductivity and Temperature are not controlled by Prismaflex
Patient Fluid [F] Removal Performance (Range)	SE	0 to 2000 ml/hr Increment: 5 ml/hr	0 to 2000 ml/hr Increment: 10 ml/hr

Table 3. Substantial Equivalence Table Device Comparison

Features	SE	Proposed PrisMax 1.0.6.0	Predicate Prismaflex 7.10, K131516
Patient Fluid Removal Performance (Accuracy)	SE	± 30 ml/hr ± 70 ml/3hr ± 300 ml/24hr Scales calibrated at ambient temperature at which they will be used. Ambient temperature change less than ±3 °C (5.4 °F) during treatment.	± 30 ml/hr ± 70 ml/3hr ± 300 ml/24hr Scales calibrated at ambient temperature at which they will be used. Ambient temperature change less than ±3 °C (5.4 °F) during treatment.
Access Pressure Sensor	SE	Range: -250 to +450 mmHg Accuracy: ±15 mmHg	Range: -250 to +450 mmHg Accuracy: ±15 mmHg
Return Pressure Sensor	SE	Range: -50 to +350 mmHg Accuracy: ±5 mmHg	Range: -50 to +350 mmHg Accuracy: ±5 mmHg
Filter Pressure Sensor	SE	Range: -50 to +450 mmHg Accuracy: ±15 mmHg	Range: -50 to +450 mmHg Accuracy: ±15 mmHg
Effluent Pressure Sensor	SE	Range: -350 to +400 mmHg (CRRT) Accuracy: ±15 mmHg	Range: -350 to +400 mmHg (CRRT) Accuracy: ±15 mmHg
Control Unit Software [G]	SE	Version 1.0.6.0	Version 7.10

Table 3**: Foot notes:**

A. Syringe Sizes: *20, 30 & 50 ml. Removed 30 ml.*

- The 30ml syringe is removed due to infrequent use in the market. The device behavior in conjunction with the specified syringes remains strictly unchanged.
- The updated specification does not affect safety or effectiveness of the device.

B. Dialysate Flow Rate: *CVVH & CVVHDF: Range: 0 to 8000 ml/hr, Increment: 10 ml/hr. Updated the increment from 50ml/hr to 10ml/hr.*

- The setting range was increased from 50 to 10ml/hr. This allows the practitioner to select a more precise setting and reduces limitation existing with a 50ml/hr increment.

The updated specification does not introduce new or increased risks to the system and does not introduce new questions of safety and effectiveness. Compliance of the PrisMax System to the updated specifications has been verified successfully. Successful validation has substantiated that the system does not raise new questions of safety and effectiveness.

C. Replacement solution / Fluid Flow Rate: *CVVH & CVVHDF: Range: 0 to 8000 ml/hr, Increment: 10 ml/hr. Updated the increment from 50ml/hr to 10ml/hr.*

- The range was increased from 50 to 10ml/hr. This allows the practitioner to select a more precise setting and reduces limitation existing with a 50ml/hr increment.

The updated specification does not introduce new or increased risks to the system and does not introduce new questions of safety and effectiveness. Compliance of the PrisMax System to the updated specifications has been verified successfully. Successful validation has substantiated that the system does not raise new questions of safety and effectiveness.

D. Pre-Blood Pump Flow Rate: *SCUF: Range: 0 to 2000 ml/hr. Align with Predicate device Prismaflex from clearances K110823 and K131516.*

- The Prismaflex SE table incorrectly states a range of 0 to 1000 ml/hr vs. the actual of 0 to 2000 ml/hr. As per Prismaflex requirement sss_1283, the predicate device has operated at the Range: 0 to 2000 ml/hr since the original clearance in 2005. The PrisMax is equivalent in practice and requirements. The Prismaflex SE table will be updated on the next submission.

The updated specification does not introduce new or increased risks to the system and does not introduce new questions of safety and effectiveness. Compliance of the PrisMax System to the updated specifications has been verified successfully. Successful validation has substantiated that the system does not raise new questions of safety and effectiveness.

E. Trans Membrane Pressure Alarms TMP (CRRT): *User settable: +70 to +350 mmHg, default +350 mmHg. Implemented fixed default of +300 mmHg.*

- User Settable TMP was removed due to infrequent use in the predicate device and to reduce risk of use-error handling during set up.
- Increase usability by removing steps during set up.
- Implement lowered default to reduce risk.

The updated specification does not introduce new or increased risks to the system and does not introduce new questions of safety and effectiveness. Compliance of the PrisMax System to the updated specifications has been verified successfully. Successful validation has substantiated that the system does not raise new questions of safety and effectiveness.

F. Patient Fluid Removal Performance (Range): 0 to 2000 ml/hr Increment: 5 ml/hr.

Updated the increment from 10ml/hr to 5ml/hr.

- Increase setting range by improving increment range of setting from 10 to 5ml/hr. This allows the practitioner to select a more precise setting and reduces limitation existing with a 10ml/hr increment.

The updated specification does not introduce new or increased risks to the system and does not introduce new questions of safety and effectiveness. Compliance of PrisMax System to the updated specifications has been verified successfully. Successful validation has substantiated that the system does not raise new questions of safety and effectiveness.

G. Control Unit Software: *Software version 1.0.6.0 or Rev. A, from Prismaflex 7.10.*

The device software on the PrisMax has been implemented correctly. The software has been verified and validated subsequent to risk analysis. The verification and validation tests including Human Factors and Software Validation. The software does not raise questions of safety and effectiveness. PrisMax is considered substantially equivalent to the predicate device Prismaflex.

Substantial Equivalence Summary

The differences between the PrisMax System and its predicate device do not introduce new questions of safety and effectiveness. All modifications have been verified and

validated per Design Controls Activities. As shown through successful verification and validation testing, the PrisMax Control Unit is considered substantially equivalent to its predicate.

DISCUSSION OF NONCLINICAL TESTS:

Performance testing was conducted on the PrisMax System to evaluate the functional performance of the system. The performance testing confirms PrisMax remains as safe and effective as Prismaflex and is substantially equivalent.

In summary, the PrisMax Control Unit has successfully implemented performance requirements and subsequent outputs verifying and validating:

- The PrisMax design validation meets the user needs and intended use and is substantially equivalent to the predicate.
- The device complies with IEC60601-2-16 Hemodialysis Equipment. Testing was confirmed by CSA, the recognized test laboratory as part of the testing to 60601-1 Edition3.1. The testing specifically confirms the device meets the requirements for Essential Performance according to the particular standard.
- Electrical safety testing according to the most recent IEC60601-1 Edition 3.1 standard. The standard includes reports for software, alarms, usability, safety and performance.
- Electromagnetic compatibility (EMC) testing.
- Risk Assessment and risk control measures. A therapy level, product level and process level hazard analysis confirms the device doesn't perform in an unexpected or unsafe manor.
- Labeling, Software including cybersecurity, Human Factors, have been successfully implemented.

SUBSTANTIAL EQUIVALENCE DECISION

Based on the the information provided in this premarket notification, Baxter Healthcare Corporation believes the proposed PrisMax is substantially equivalent, for purposes of section 510(k) of the Federal Food, Drug and Cosmetic Act only, to the predicate device identified in this premarket notification.