March 13, 2020

Baxter Healthcare Corporation
Christopher Scavotto
Senior Manager, Global Regulatory Affairs
7601 Northland Drive
Brooklyn Park, MN 55428

Re: K193482
Trade/Device Name: PrisMax System Version 3
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: December 16, 2019
Received: December 17, 2019

Dear Christopher 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. 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,

Carolyn Y. Neuland, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193482

Device Name

PrisMax System Version 3

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.
• Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K193482 510(k) Summary

December 16th, 2019

SUBMITTER / OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

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IDENTIFICATION OF THE DEVICE:

Common Name: Hemodialysis Delivery System
Trade Name or Proprietary Name: PrisMax System Version 3
Classification Panel: 78 Gastroenterology and Urology
Classification: High Permeability Hemodialysis System (876.5860)
Class: Class II
Product Code: KDI

Table 1. Product Code(s) for PrisMax System

Code Number	Name
955724	PrisMax System Version 3

PREDICATE DEVICE:

Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
PrisMax System Version 2	Baxter Healthcare, Gambro UF Solutions, Inc.	K190910	July 2019

DEVICE DESCRIPTION:

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 premarket notification (510(k)), consists of the PrisMax System Version 3. The proposed device PrisMax System Version 3 uses the current marketed device PrisMax System Version 2 as the predicate. The device has been cleared within the last year.

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.
- Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Substantial Equivalence Summary

The differences between the PrisMax System Version 3 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 System is considered substantially equivalent to its predicates. Reference Table 3.

Table 3. Substantial Equivalence Table

Features	SE	Proposed K19XXXX PrisMax Version 3	Proposed K190910 PrisMax Version 2
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. • Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of	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. • Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of

Table 3. Substantial Equivalence Table

Features	SE	Proposed K19XXXX PrisMax Version 3	Proposed K190910 PrisMax Version 2
		plasma components is indicated. All treatments administered via the Prismaflex control unit must be prescribed by a physician.	plasma components is indicated. 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 TPE: TPE 2000 Set	For CRRT: M60/M100/M150 HF1000 & HF1400 For TPE: TPE 2000 Set
Syringe Sizes	SE	20 & 50 ml	20 & 50 ml
Anticoagulation	SE	User-controllable as continuous or bolus	User-controllable as continuous or bolus
Dialysate Flow Rate	SE	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 10 ml/hr	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 10 ml/hr
Dialysate Flow Rate Accuracy	SE	± 30 ml/hr	± 30 ml/hr
Replacement solution / Fluid Flow Rate	SE	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 10 ml/hr TPE: Range: 0 to 5000 ml/hr Increment: 10 ml/hr	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 10 ml/hr TPE: Range: 0 to 5000 ml/hr Increment: 10 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
Pre-Blood Pump Flow Rate	SE	SCUF: Range: 0 to 2000 ml/hr	SCUF: Range: 0 to 2000 ml/hr

Table 3. Substantial Equivalence Table

Features	SE	Proposed K19XXXX PrisMax Version 3	Proposed K190910 PrisMax Version 2
		CVVH, CVVHD, CVVHDF: Range: 0 to 4000 ml/hr TPE Range Range: 0 to 1000 ml/hr Note: PBP Volume is 2000 ml/treatment for TPE2000	CVVH, CVVHD, CVVHDF: Range: 0 to 4000 ml/hr TPE Range Range: 0 to 1000 ml/hr Note: PBP Volume is 2000 ml/treatment for TPE2000
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 TPE	SCUF CVVH CVVHD CVVHDF TPE
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 Pump (PBP)	Dialysate Replacement Effluent Pre Blood Pump (PBP)
Trans Membrane Pressure TMP Alarms (CRRT) TMPa (TPE)	SE	CRRT TMP: Default: +300 mmHg TMPa: User settable; +50 to +100 mmHg Default: +100 mmHg	CRRT TMP: Default: +300 mmHg TMPa: User settable; +50 to +100 mmHg Default: +100 mmHg
Dialysate Conductivity and Temperature	SE	Dialysate Conductivity and Temperature are not controlled by PrisMax	Dialysate Conductivity and Temperature are not controlled by PrisMax
Patient Fluid Removal	SE	CRRT: 0 to 2000 ml/hr	CRRT: 0 to 2000 ml/hr

Table 3. Substantial Equivalence Table

Features	SE	Proposed K19XXXX PrisMax Version 3	Proposed K190910 PrisMax Version 2
Performance (Range)		Increment: 5 ml/hr TPE: 0 to 1000 ml/hr Increment: 5 ml/hr	Increment: 5 ml/hr TPE: 0 to 1000 ml/hr Increment: 5 ml/hr
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) -350 to +400 mmHg (TPE) Accuracy: ±15 mmHg	Range: -350 to +400 mmHg (CRRT) -350 to +400 mmHg (TPE) Accuracy: ±15 mmHg
TPE Specific Settings	SE	Patient Hematocrit Range: 10 to 60% Increment: 1% Default: 30%	Patient Hematocrit Range: 10 to 60% Increment: 1% Default: 30%
TPE Specific Settings	SE	Total Replacement Volume Range: 0 to 10,000 ml Increment: 1 ml Default: 0 ml	Total Replacement Volume Range: 0 to 10,000 ml Increment: 1 ml Default: 0 ml
TPE Specific Settings	SE	Patient Plasma Loss Rate Range: 0, or 10 to 1000 ml/hr Increment: 5 ml/hr Default: 0 ml/hr	Patient Plasma Loss Rate Range: 0, or 10 to 1000 ml/hr Increment: 5 ml/hr Default: 0 ml/hr
TPE Specific Settings	SE	Replacement Container Volume Range: 0 to 5000 ml Increment: 0.1 ml	Replacement Container Volume Range: 0 to 5000 ml Increment: 0.1 ml
Control Unit Software [A]	SE	PrisMax Version 3	PrisMax Version 2
Blood Warmer Accessory	SE	Prismatherm Warmer	Prismatherm Warmer

Table 3. Substantial Equivalence Table

Features	SE	Proposed K19XXXX PrisMax Version 3	Proposed K190910 PrisMax Version 2
		PrismaFlo Blood Warmer Prismacomfort Blood Warmer TherMax Blood Warmer	PrismaFlo Blood Warmer Prismacomfort Blood Warmer TherMax Blood Warmer

TABLE 3: FOOT NOTES:

1. DISCUSSION OF WHY DIFFERENCES DON'T RAISE NEW QUESTIONS OF SAFETY AND EFFECTIVENESS

[A] Control Unit Software: Software Version 3 from Software Version 2.

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.

The updated specifications do 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.

2. SUBSTANTIAL EQUIVALENCE SUMMARY

The differences between the PrisMax System Version 3 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 System Version 3 is considered substantially equivalent to its predicate.

3. 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 devices identified in this premarket notification.

4. MEANING OF SUBSTANTIAL EQUIVALENCE

The term "substantial equivalence" is only used herein in the premarket notification and supporting information to indicate substantial similarity to predicate products to refer to the standard by which the U.S. Food and Drug Administration reviews and clears certain devices through the 510(k) process pursuant to the Federal Food, Drug and Cosmetic Act. The term "equivalence," as used in this premarket submission, is not intended to relate to or suggest the use of the term "equivalence" or similar terminology in the context of any factual or legal determination in the patent law context.

PERFORMANCE DATA

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 the predicates and is substantially equivalent. Below are high level summary of tests used to demonstrate substantial equivalence along with FDA guidance's and FDA recognized consensus standards.

In summary, the PrisMax System 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 UL, 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 according to the most recent IEC60601-1-2 Edition 4 standard.
- Software Verification and Validation testing were conducted and documentation was provided as recommended by FDA's guidance "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices". The software for this device was considered as a "major" level of concern.

- 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 in accordance with FDA Guidance's.

DISCUSSION OF CLINICAL TESTS:

There are no clinical tests submitted, referenced or relied on in this premarket notification submission for a determination of substantial equivalence for the PrisMax device or its predicate.

CONCLUSIONS

Based on the the information provided in this premarket notification, Baxter Healthcare Corporation concludes and 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 devices identified in this premarket notification. The device is as safe, as effective and performs as well as the legally marketed Predicate device.

The nonclinical data demonstrate that the PrisMax System Version 3 performs comparably to the predicate devices that is currently marketed for the same intended use.