February 23, 2018

Baxter Healthcare Corporation
Rick Lukacovic
Manager, Regulatory Affairs
32650 North Wilson Road
Round Lake, IL 60073

Re: K171671
Trade/Device Name: Prismaflex System 8.10
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Dated: January 23, 2018
Received: January 26, 2018

Dear Rick Lukacovic:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -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)*

K171671

Device Name

Prismaflex System 8.10

Indications for Use *(Describe)*

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.
• 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 Prismaflex 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5. 510(k) Summary

1. SUBMITTER'S NAME:

Baxter Healthcare Corporation
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Deerfield, Illinois 60015

Establishment Registration #: 1416980

2. CONTACT PERSON:

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Round Lake, IL 60073
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3. IDENTIFICATION OF THE DEVICE:

Trade/Device Name: Prismaflex System 8.10
Classification Panel: Gastroenterology/Urology
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system.
Regulatory Class: II
Product Code: KDI

This submission for Prismaflex System 8.10 is a change to the Prismaflex Control Unit which has been updated to Software Version 8.10 and has undergone hardware and labeling changes. None of these changes affect the performance parameters discussed in Table 2 Substantial Equivilence Table.

4. PREDICATE DEVICE:

Device	Predicate 510(k)	Clearance Date
Prismaflex System 7.10	K131516	January 3, 2014

5. DESCRIPTION OF THE DEVICE:

The Prismaflex control unit is a software controlled device that performs the following functions:

Loads and primes the Prismaflex disposable set automatically.

- Pumps blood through the blood flow path of the Prismaflex disposable set.
- Delivers anticoagulant solution into the blood flow path.
- Pumps sterile infusion solutions into the blood flow path of the Prismaflex disposable set according to therapy in use.
- Pumps sterile dialysate into the fluid compartment of the filter in CRRT therapies.
- Controls the patient fluid removal or plasma loss according to the therapy in use.
- Monitors the system and alerts the operator to abnormal situations through alarms.
- Provides treatment data to an external Patient Data Management Systems (PDMS)

Physical characteristics of Prismaflex Control Unit

Table 1. Physical Characteristics

Weight	Approximately 78 kg (172 lb) (without fluid bags and Prismaflex disposable set)
Height	Approximately 163 cm (64 in)
Width	Approximately 49 cm (19 in)
Base	Approximately 70 cm x 70 cm (28 in x 28 in)

5.1 INDICATIONS FOR USE:

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.
- 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 Prismaflex control unit must be prescribed by a physician.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

In Table 2 the Prismaflex System 8.10 is compared with the predicate Prismaflex System 7.10

Table 2. Substantial Equivelence Table

Devices	Predicate Prismaflex System 7.10 K131516	Device Prismaflex System 8.10	Difference
Indication for Use	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. 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 Prismaflex 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. 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 Prismaflex control unit must be prescribed by a physician.	same
Dedicated Disposable Sets Available in U.S.	For CRRT: M60/M100/M150 HF1000 & HF1400 For TPE: TPE 2000 Set	For CRRT: M60/M100/M150 HF1000 & HF1400 For TPE: TPE 2000 Set	same
Syringe	20, 30 & 50 ml	20, 30 & 50 ml	same
Anticoagulation	User-controllable as continuous or bolus	User-controllable as continuous or bolus	same
Dialysate Flow Rate	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 50 ml/hr	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 50 ml/hr	same
Dialysate Flow Rate Accuracy	± 30 ml/hr	± 30 ml/hr	same

Table 2. Substantial Equivelence Table

Devices	Predicate Prismaflex System 7.10 K131516	Device Prismaflex System 8.10	Difference
Replacement solution / Fluid Flow Rate	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 50 ml/hr TPE: Range: 0 to 5000 ml/hr Increment: 10 ml/hr	CVVH & CVVHDF: Range: 0 to 8000 ml/hr Increment: 50 ml/hr TPE: Range: 0 to 5000 ml/hr Increment: 10 ml/hr	same
Replacement Flow Rate Accuracy	± 30 ml/hr	± 30 ml/hr	same
Blood Flow Rate	Range: 10-450 ml/min.	Range: 10-450 ml/min.	same
Blood Flow Rate Accuracy	±10% of user set rate at nominal blood flow of 450 ml/min or the highest achievable disposable blood flow at 37° C 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 at 37° C at an access pressure of -200 mmHg and without any PBP flow.	same
Pre-Blood Pump Flow Rate	CRRT Range Range: 0 to 4000 ml/hr TPE Range Range: 0 to 1000 ml/hr Note: Total PBP Volume is 2000 ml/treatment for TPE	CRRT Range Range: 0 to 4000 ml/hr TPE Range Range: 0 to 1000 ml/hr Note: Total PBP Volume is 2000 ml/treatment for TPE	same
Pre-Blood Pump Accuracy	± 30 ml/hr	± 30 ml/hr	same
Effluent Pump Flow Rate	0 to 10000 ml/hr depending on the therapy	0 to 10000 ml/hr depending on the therapy	same
ECG Discharger	YES	YES	same

Table 2. Substantial Equivelence Table

Devices	Predicate Prismaflex System 7.10 K131516	Device Prismaflex System 8.10	Difference
Therapies	SCUF CVVH CVVHD CVVHDF TPE	SCUF CVVH CVVHD CVVHDF TPE	same
Pumps	PBP solution Replacement solution Dialysate solution Effluent Blood	PBP solution Replacement solution Dialysate solution Effluent Blood	same
Scales	Dialysate Replacement Effluent Pre blood (PBP)	Dialysate Replacement Effluent Pre blood (PBP)	same
Transmembrane Pressure TMP (CRRT) TMPa (TPE)	TMP: User settable: +70 to +350 mmHg Default: +350 mmHg TMPa: User settable; +50 to +100 mmHg Default: +100 mmHg	TMP: User settable: +70 to +350 mmHg Default: +350 mmHg TMPa: User settable; +50 to +100 mmHg Default: +100 mmHg	same
Dialysate Conductivity and Temperature	Dialysate Conductivity and Temperature are not controlled by Prismaflex	Dialysate Conductivity and Temperature are not controlled by Prismaflex	same
Patient Fluid Removal Performance Range	0 to 2000 ml/hr maximum for **CRRT** 0 to 1000 ml/hr for TPE Increment: 10 ml/hr	0 to 2000 ml/hr maximum for **CRRT** 0 to 1000 ml/hr for TPE Increment: 10 ml/hr	same
Patient Fluid Removal Performance Range Accuracy	± 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.	same

Table 2. Substantial Equivelence Table

Devices	Predicate Prismaflex System 7.10 K131516	Device Prismaflex System 8.10	Difference
Access Pressure and Accuracy	Range -250 to +450 mmHg Accuracy ±15 mmHg	Range -250 to +450 mmHg Accuracy ±15 mmHg	same
Return Pressure and Accuracy	Range -50 to +350 mmHg Accuracy ±5 mmHg	Range -50 to +350 mmHg Accuracy ±5 mmHg	same
Filter Pressure Sensor	Range -50 to +450 mmHg Accuracy ±10% of reading or ±8 mmHg	Range -50 to +450 mmHg Accuracy ±10% of reading or ±8 mmHg	same
Effluent Pressure Sensor	Range -350 to +400 mmHg (CRRT) Range -350 to +350 mmHg (TPE) Accuracy ±10% of reading or ±8 mmHg	Range -350 to +400 mmHg (CRRT) Range -350 to +350 mmHg (TPE) Accuracy ±10% of reading or ±8 mmHg	same
TPE Settings:	Pre-treatment Hematocrit Range: 10 to 60% Increment: 1% Default: 30%	Pre-treatment Hematocrit Range: 10 to 60% Increment: 1% Default: 30%	same
TPE Settings	Total Replacement Volume Range: 0 to 10,000 ml Increment: 100 ml Default: 3000 ml	Total Replacement Volume Range: 0 to 10,000 ml Increment: 100 ml Default: 3000 ml	same
TPE Settings	Patient Plasma Loss Rate Range: 0, or 10 to 1000 ml/hr Increment: 10 ml/hr Default: 0 ml/hr	Patient Plasma Loss Rate Range: 0, or 10 to 1000 ml/hr Increment: 10 ml/hr Default: 0 ml/hr	same
TPE Settings	Replacement Container Volume Range: 0 to 5000 ml Increment: 10 ml	Replacement Container Volume Range: 0 to 5000 ml Increment: 10 ml	same

7. DISCUSSION OF NONCLINICAL TESTS:

Testing was performed for the Prismaflex System 8.10, in order to determine substantial equivalence with predicate devices included:

- Software and system verification and validation including functional, performance and safety requirements; see section 16 for a summary and referenced reports

Compliance has been demonstrated to the following international standards ;

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8: Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-16: Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment
- IEC 62304: Medical device software - Software life cycle processes
- IEC 62366: Medical devices -- Application of usability engineering to medical devices

8. BIOCOMPATIBILITY:

The Prismaflex Control Unit is not in direct contact with patient. Patient contact is via 510(k) cleared or PMA approved medical devices.

9. STERILITY AND SHELF LIFE:

The Prismaflex Control Unit is not sold as sterile and therefore this section is not applicable. This device does not claim an expiration date.

10. CONCLUSION:

The successful testing of the Prismaflex System 8.10 demonstrates safety and effectiveness when used for the defined indications for use and is substantially equivalent to the predicate devices.