April 1, 2022

Baxter Healthcare Corporation
% Maud Humbert
Senior Manager, Global Regulatory Affairs
Gambro Industries
7 Avenue Lionel Terray, BP 126
Meyzieu, F-69883
FRANCE

Re: K212216
Trade/Device Name: Prismaflex ST set (ST60/ST100/ST150 sets)
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: February 18, 2022
Received: March 3, 2022

Dear Maud Humbert:

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
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)*
K212216

Device Name
Prismaflex ST set

Indications for Use *(Describe)*

The Prismaflex ST set is a single use device that provides blood purification through a semipermeable membrane.

The Prismaflex ST set is for use only in conjunction with the PrismaFlex control unit or with the PrisMax control unit (in countries where PrisMax is cleared or registered).

All treatments administered via the PrismaFlex ST sets must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

If patients suffer from acute kidney injury and / or volume overload, the Prismaflex ST set is indicated for continuous renal replacement therapies (CRRT), in modalities such as:

- Slow Continuous UltraFiltration (SCUF)
- Continuous Veno-Venous Hemofiltration (CVVH)
- Continuous Veno-Venous HemoDialysis (CVVHD)
- Continuous Veno-Venous HemoDiaFiltration (CVVHDF)

to perform fluid management and reduction of uremic toxins.

The Prismaflex ST100 and ST150 set is indicated for use in patients with a body weight equal or greater than 30 kg (66lb) and Prismaflex ST60 set is indicated to patients with a body weight greater than 11kg (24lb).

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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Baxter

510(k) Summary

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Date of Preparation: February 15, 2022

IDENTIFICATION OF THE DEVICE:

Common Name: High Permeability Hemodialyzer

Trade/Device Name: Prismaflex ST Set

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. Code Numbers for Prismaflex ST set

Code Number	Name
107643US	Prismaflex ST60 set
107636US	Prismaflex ST100 set
107640US	Prismaflex ST150 set

PREDICATE DEVICE:

Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
K041005	Gambro Industries, France	Prismaflex M60 and M100 sets	10/18/2004

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Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
K080519	Gambro Industries, France	Prismaflex M150 set	06/13/2008
K190910	Gambro Industries, France	Prismaflex M60, M100 and M150 sets (intended for use with Prismax system)	07/25/2019

DESCRIPTION OF THE DEVICE:

The Prismaflex ST60/ST100/ST150 set is a disposable, extracorporeal circuit for use with the PrismaFlex system, or with the PrisMax system. The Prismaflex ST60/ST100/ST150 set consists of an AN69 ST hollow fiber haemofilter/dialyser and tubing system.

These Prismaflex disposable sets allow the following fluid management and renal replacement therapies to be performed :

- SCUF: Slow Continuous Ultrafiltration
- CVVH: Continuous Veno-Venous Hemofiltration
- CVVHD: Continuous Veno-Venous Hemodialysis
- CVVHDF: Continuous Veno-Venous Hemodiafiltration

The fluid pathways of the Prismaflex set are guaranteed sterile and pyrogen-free. The Prismaflex set is sterilized by ethylene oxide (EO).

The shelf life of the Prismaflex ST60/ST100/ST150 sets is 24 months from the date of sterilization. The device is intended for single use.

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All treatments administered via the PrismaFlex ST sets must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical

condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

If patients suffer from acute kidney injury and / or volume overload, the Prismaflex ST set is indicated for continuous renal replacement therapies (CRRT), in modalities such as:

- Slow Continuous UltraFiltration (SCUF)
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- Continuous Veno-Venous HemoDiaFiltration (CVVHDF)

  to perform fluid management and reduction of uremic toxins.

The Prismaflex ST100 and ST150 set is indicated for use in patients with a body weight equal or greater than 30 kg (66lb) and Prismaflex ST60 set is indicated to patients with a body weight greater than 11kg (24lb).

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The Prismaflex ST set has the same intended use and the same technological characteristics compared to its predicate, the Prismaflex M set, in term of design, material, chemical composition, function and operation.

The safety and performance of Prismaflex ST set was evaluated through non-clinical testing. The bench and pre-clinical testing assessed the following aspects of the device:

- Structural integrity
- Membrane integrity
- Ultrafiltration rate
- Clearances
- Sieving coefficients
- Blood pressure drop
- Total volume of blood in the set
- Priming efficacy
- Shelf life
- Sterilization validation

- Pyrogenicity / LAL
- EO residuals
- Biocompatibility

DISCUSSION OF NONCLINICAL TESTS:

Performance Data:

Performance testing was conducted on the Prismaflex ST set to evaluate the functional performance of the device. In summary, the Prismaflex ST set has successfully implemented performance requirements and subsequent outputs verifying and validating:

- The Prismaflex ST set design validation meets the user needs and intended use and is substantially equivalent to the predicate.
- The device complies with the standard ISO 8637-1 First edition 2017-11, Extracorporeal systems for blood purification ¬ Part 1:Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators. The testing specifically confirms the device meets the requirements for the mechanical characteristics (structural and blood compartment integrity), and the performance characteristics (solute clearances, sieving coefficients, ultrafiltration coefficient, volume and pressure drop of blood compartment, expiry date) according to this particular standard. The standard also includes requirements for biological safety, sterility and non pyrogenicity.
- The device also complies with the standard ISO 8638 Third edition 2010-07-01, Cadiovascular implants and extracorporeal blood circuit for hemodialyzers hemodialfilters and hemofilters. The standard includes requirements for biological safety, sterility, non pyrogenicity, mechanical characteristics, expiry date and tubing compliance.
- The labeling has been successfully implemented and meets the requirements of the above-mentioned standards.
- Risk Assessment and control measures: The risk analysis confirms the device is appropriatly designed and performs as expected and in a safe manner.

Biocompatibility:

The biocompatibility evaluation for this device was conducted in accordance with ISO-10993-1 Fifth edition 2018-08, “Biological evaluation of medical devices Part 1:

Evaluation and testing within a risk management process," as recognized by FDA and FDA guidance document Use of International Standard ISO-10993-1, "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity (per ISO 10993-5)
- Sensitization (per ISO 10993-10)
- Intracutaneous (Irritation) Reactivity (per ISO 10993-10)
- Acute Systemic Toxicity (per ISO 10993-11)
- Material Mediated Pyrogen (per ISO 10993-11)
- Subacute/Subchronic Toxicity (per ISO 10993-11)
- Hemolysis (per ISO 10993-4)

CONCLUSION:

The summary includes the conclusions drawn from the nonclinical tests (discussed above) that demonstrate that the Prismaflex ST set is as safe, as effective, and performs as well as the predicate device.

The non-clinical data demonstrate that the subject device is substantially equivalent and performs comparably to the predicate device that is currently marketed for the same intended use.