January 21, 2022

Baxter Healthcare Corporation
% Alberto Pancanti
Manager, Global Regulatory Affairs
Gambro Dasco S.p.A
via Modenese 66
Medolla, Modena 41037
ITALY

Re: K213639
Trade/Device Name: Revaclear 500, Revaclear 400, Revaclear 300
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: November 17, 2021
Received: November 18, 2021

Dear Alberto Pancanti:

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)*

K213639

Device Name
Revaclear 300
Revaclear 400
Revaclear 500

Indications for Use *(Describe)*

Revaclear hemodialyzers/diafilters are intended to purify blood in hemodialysis and hemodiafiltration
Revaclear devices are indicated for the treatment of chronic or acute renal failure

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

Nov 17, 2021

OWNER:

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IDENTIFICATION OF THE DEVICE:

Common Name :	Dialyzer, high permeability with or without sealed dialysate system
Trade/Device Name:	Revaclear (Models 300, 400, 500)
Regulation Number:	21 CFR 876.5860
Regulation Name:	High permeability hemodialysis system
Regulatory Class:	Class II
Product Code:	KDI
Classification Panel:	78 Gastroenterology and Urology

Table 1. Proposed Device

Device	Company
Revaclear 500 (new and representative device for this Pre-Market Notification 510(k)) Revaclear 400 (currently cleared under K130039) Revaclear 300 (currently cleared under K130039)	Gambro Dialysatoren GmbH[1]
[1] Acquired by Baxter Healthcare	

PREDICATE DEVICE:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Polyflux 210H	Gambro Dialysatoren GmbH[1]	K030592[2]	05/23/2003
[1] Acquired by Baxter Healthcare [2] K030592 includes the Polyflux 140H, Polyflux 170H, and Polyflux 210H. Polyflux 210H was chosen as the predicate device as it is the most similar in size to the proposed device.			

REFERENCE DEVICE FOR THE TECHNONOGICAL AND BIOLOGICAL CHARACTERISTICS OF THE PROPOSED DEVICE:

Table 3. Reference Device

Device	Company	Reference 510(k) / 513(f)(2) (De Novo)	Clearance Date
Revaclear 400	Gambro Dialysatoren GmbH[1]	K130039[1]	05/02/2013
Theranova 500	Gambro Dialysatoren GmbH[2]	DEN1900422	08/28/2020
[1] K130039 included the Revaclear 300 and Revaclear 400. Revaclear 400 was chosen as the technological reference device as it has the same fundamental technological characteristics as the proposed device. [2] DEN190042 included the Theranova 400 and Theranova 500. Theranova 500 was chosen as the biological device as it is made up of the same material as the proposed device.			

DESCRIPTION OF THE DEVICE:

The Revaclear hemodialyzers/diafilters are intended to purify blood in hemodialysis and hemodiafiltration.

Revaclear devices are for single use, steam sterilized with sterile and non-pyrogenic fluid pathways.

Revaclear devices are part of an extracorporeal system for dialysis treatments to be used under care of trained professionals of dialysis centers or hospitals.

The Revaclear hemodialyzer family uses the hollow fiber dialyzer technology, which is an existing technology that has been on the market for almost 50 years. The mechanism of action and principles of operation of the hemodialyzer device are as follows:

Blood enters a blood inlet port, where it is distributed into membrane hollow fibers. At either end of the device, the membrane hollow fibers are potted in polyurethane to isolate the blood compartment from the dialysate compartment. (one sentence removed) By means of hydrostatic pressure, or transmembrane pressure (which is created by a combination of positive and negative pressures across the membrane), water along with certain low molecular weight solutes of the plasma pass through the membrane to the filtrate or dialysate compartment of the device. Toxins and waste products are removed from the patient's blood by means of diffusion and convection; they are eliminated via the dialysate/filtrate and the membrane during the treatment session. The dialysate exits the device via a dialysate/filtrate outlet port.

Diffusion is the major transport mechanism for urea and other small molecules, while convective transport mainly removes large uremic molecules. Convective transport is driven by the fluid flow across the membrane. Fluid balance is controlled by a dialysis monitor that can control ultrafiltration (UF) to achieve the prescribed net weight loss (ultrafiltration UF). In HDF excess UF across the membrane is accomplished thereby enhancing the middle molecule removal in comparison to HD. The excess UF applied during HDF treatments necessitates a corresponding infusion of a substitution fluid controlled by the monitor.

The basis for this premarket notification is a modification to the Revaclear product line

The modifications consist of

1. adding a new size, Revaclear 500, to the product family currently made up of Revaclear 300 and Revaclear 400 hemodialyzers. The Revaclear 500 design has a

larger diameter housing and an increase in the number of hollow fibers as compared to the biggest size of the current product family, Revaclear 400. The Revaclear 500, being the new proposed device, has been considered the representative device of the entire Revaclear products family for this Pre-Market Notification 510(k)

2. updating the indication for use for all the sizes, as suggested by FDA in the previous Pre-Market Notification 510(k) submitted for Revaclear 500 (K180790) The intent of this premarket submission is to have a unique 510(k) pre-market notification for all the Revaclear family devices, inclusive of Models 300, 400, and 500

Baxter proposes to harmonize the indication for use between in the USA and outside of the USA to one uniform indication, applicable worldwide, and consequently the labeling elements for Revaclear products family (Models 300, 400 and, 500) and to split the Indications for use into Intended Use/Purpose and Indication for clarity purpose, as per the following:

INTENDED USE / PURPOSE

Revaclear hemodialyzers/diafilters are intended to purify blood in hemodialysis and hemodiafiltration .

INDICATION

Revaclear devices are indicated for the treatment of chronic or acute renal failure.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The Revaclear 500 device has the same intended use as the predicate device, Gambro Polyflux 210H, excluding hemofiltration.

The Revaclear 500 device, labelled for single use, has the same design, materials, manufacturing process and function as the technological reference device, Revaclear 400 device. The predicate device, the Gambro Polyflux 210H, and technological reference device, the Revaclear 400 device, have been cleared for marketing in the United States under 510(k) premarket notifications K030592 and K130039, respectively. The intended population of the Revaclear 500 is identical to the predicate device, excluding patients requiring hemofiltration treatment.

The membrane material used in the Revaclear 500 Device is a blend of polyarylethersulfone (PAES) and polyvinylpyrrolidone (PVP) which is identical to the membrane utilized in the technological reference devices Revaclear 400 and in the biological reference device Theranova 500.

Theranova 500 was granted marketing authorization under 513(f)(2) De Novo DEN190042 on Aug 28th 2020.

Table 4 provides a comparison of the proposed devices, the predicate device, and the technological and biological reference devices. These comparisons identify similarities and differences of the proposed devices to the current legally marketed devices to which substantial equivalency is claimed in terms of Indications for Use, Technological and Biological Characteristics.

Table 4. Device Comparison for Proposed Device, Predicate Device, Technological and Biological Reference Devices

Features	Predicate Device Gambro Polyflux 210H (K030592)	Technological Reference Device Revaclear 400 (K130039)	Biological Reference Device Theranova 500 (DEN190042)	Proposed Device All Revaclear Models
Intended Use	The capillary dialyzer/filter is intended for use in hemodialysis, hemodiafiltration and hemofiltration for the treatment of chronic or acute renal failure	Revaclear 400 is indicated for treatment of chronic and acute renal failure by Hemodialysis.	Theranova 500 dialyzer is indicated for treatment of chronic kidney failure by intermittent hemodialysis.	Revaclear hemodialyzers/diafilters are intended to purify blood in hemodialysis and hemodiafiltration
Indications for Use	The capillary dialyzer/filter is intended for use in hemodialysis, hemodiafiltration and hemofiltration for the treatment of chronic or acute renal failure.	Revaclear 400 is indicated for treatment of chronic and acute renal failure by Hemodialysis.	Theranova 500 dialyzer is indicated for treatment of chronic kidney failure by intermittent hemodialysis.	Revaclear devices are indicated for the treatment of chronic or acute renal failure..
Sterile	Yes	Yes	Yes	Same
Non-Pyrogenic	Yes	Yes	Yes	Same
Single Use	Yes	Yes	Yes	Same

Features	Predicate Device Gambro Polyflux 210H (K030592)	Technological Reference Device Revaclear 400 (K130039)	Biological Reference Device Theranova 500 (DEN190042)	Proposed Device All Revaclear Models
Materials				
Hollow fiber membrane	Blend of Polyarylethersulfone (PAES), Polyvinylpyrrolidone (PVP), and Polyamide (PA)	Blend of Polyarylethersulfone (PAES) Polyvinylpyrrolidone (PVP)	Blend of Polyarylethersulfone (PAES) Polyvinylpyrrolidone (PVP)	Same
Potting material	Polyurethane (PUR)	Polyurethane (PUR)	Polyurethane (PUR)	Same
Housing	Polycarbonate (PC)	Polycarbonate (PC)	Polycarbonate (PC)	Same
Header	Polycarbonate (PC)	Polycarbonate (PC)	Polycarbonate (PC)	Same
Gasket / O-ring	Silicone rubber (SIR)	Silicone rubber (SIR)	Silicone rubber (SIR)	Same
Supporting ring	Polypropylene (PP)	Polypropylene (PP)	Polypropylene (PP)	Same

DISCUSSION OF NONCLINICAL TESTS:

Testing was conducted on the proposed devices, Revaclear 300, 400, 500. All test results meet the acceptance criteria, and support that the proposed device is appropriately designed for its intended use.

Performance Data:

The performance characteristics of the Revaclear 500 device were determined according to the requirements of ISO 8637-1:2017 - Extracorporeal systems for blood purification - Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators. Table 5 contains the performance testing completed on the proposed devices, Revaclear 300, 400, 500. Based on performance test results, the Revaclear 500 device performs as expected for its intended use in hemodialysis and hemodiafiltration for chronic and acute treatment of renal disease.

Table 5 . Performance Testing Summary

Test	Acceptance Criteria	Results
Urea clearance	Tested in accordance to ISO 8637-1:2017	<Pass>
Creatinine clearance	Tested in accordance to ISO 8637-1:2017	<Pass>
Vitamin B12 clearance	Tested in accordance to ISO 8637-1:2017	<Pass>

Table 5 . Performance Testing Summary

Test	Acceptance Criteria	Results
Phosphate clearance	Tested in accordance to ISO 8637-1:2017	<Pass>
Flow resistance of blood compartment	Tested in accordance to ISO 8637-1:2017	<Pass>
Flow resistance of dialysate compartment	Tested in accordance to ISO 8637:2004	<Pass>
Ultrafiltration coefficient (UFC)	Tested in accordance to ISO 8637-1:2017	<Pass>
Sieving coefficient	Tested in accordance to ISO 8637-1:2017	<Pass>
Ultrafiltration rate	Tested in accordance to ISO 8637-1:2017	<Pass>

Biocompatibility:

Biocompatibility assessments have been conducted based on ISO-10993 Biological Evaluation of Medical Devices and FDA Guidance: Use of International Standard ISO 10993-1, issued September 4, 2020 to the category of external communicating device, body contact with circulating blood and long-term (> 30 days) contact duration. The battery of biological testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation/ intracutaneous reactivity
- Material Mediated Pyrogenicity
- Systemic toxicity (acute)
- Repeat dose systemic toxicity (30-days)
- Genotoxicity
- Hemocompatibility

In addition, chemical analyses were performed to characterize the materials and to identify and quantify potential leachables as recommended by ISO 10993-1 and ISO 10993-18. A toxicological risk assessment was performed per ISO 10993-17.

Based on chemical and biological test results, the Revaclear 500 Device is appropriate for its intended use in hemodialysis and hemodiafiltration for chronic and acute treatment of renal failure.

Sterility:

The Revaclear 500 device is sterilized using a Terminal Moist Heat Sterilization process and achieves a Sterility Assurance Level (SAL) of 10^{-6}. The Revaclear 500 sterilization process conforms to ISO 17665-1:2006 Sterilization of Health Care Products -- Moist Heat -- Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices.

Shelf Life:

The Revaclear devices has been tested to provide a three (3) year shelf-life claim.

CONCLUSION:

Testing performed on the Revaclear 500 indicates that the device is substantially equivalent and performs comparably to the technological and biological reference devices that are currently marketed. Apart from hemofiltration, the same Intended use and Indications is claimed for the proposed device compared to the predicate device. The Revaclear hemodiayzers family (Models 300, 400, and 500) are substantially equivalent to the predicate device.