March 10, 2021

Baxter Healthcare Corporation
Kristen Bozzelli
Manager, Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, Illinois 60073

Re: K201809
Trade/Device Name: AK 98 Dialysis Machine,
U9000 Ultrafilter,
C705 Expansion Chamber Accessory
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, FIP, FJK
Dated: February 5, 2021
Received: February 9, 2021

Dear Kristen Bozzelli:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201809

Device Name
Baxter AK 98 Dialysis Machine

Indications for Use *(Describe)*
The Baxter AK 98 dialysis machine is intended to be used for intermittant haemodialysis and/or isolated ultrafiltration treatments of patients with chronic or acute renal failure or fluid overload upon prescription by a physician.
The AK 98 dialysis machine is indicated to be used on patients with a body weight of 25 kg or more. The AK 98 dialysis machine is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis or hospital care environment. The Baxter AK 98 dialysis machine is not intended for Selfcare or Home use.

[CONTINUED ON THE NEXT PAGE]

Device Name: Baxter C-705 Accessory Expansion Chamber

C-705 Accessory Expansion Chamber is a single use sterile medical device intended to be used during the delivery of Hemodialysis treatment in Single Needle mode, on patients affected by chronic renal failure. The C-705 Accessory Expansion Chamber is an ancillary device used to allow the conversion from Double Needle to Single Needle administration mode of treatments, after connection to proper Blood Tubing System intended for Haemodialysis treatment in Double Needle mode and to a Dialyzer filter. C-705 Accessory Expansion Chamber shall be used in combination with Blood Tubing System suitable for AK 98 haemodialysis delivery system only. The total extracorporeal blood volume for the extracorporeal circuit including the set, dialyzer and accessories should represent less than 10% of the patient's blood volume.

[CONTINUED ON THE NEXT PAGE]

Device Name: Baxter U9000 Ultrafilter

The U9000 Ultrafilter is indicated for purification of incoming water for dialysis fluid as well as purification of dialysis fluid to obtain standard dialysis fluid in accordance with international standards requirements and local regulations. The risk of exposure to bacteria and endotoxins can thereby be minimized. The U9000 Ultrafilter is intended to be used in conjunction with a water treatment system.

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

10 March, 2021

OWNER:

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IDENTIFICATION OF THE DEVICES:

Common Name: Hemodialysis Delivery System
Trade/Device Name: AK 98
Classification Panel: 78 Gastroenterology and Urology
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: 78KDI

Common Name: Ultrafilter/Water Purification Subsystem
Trade/Device Name: U9000
Classification Panel: 78 Gastroenterology and Urology
Regulatory Class: Class II
Product Code: 78FIP

Common Name: : Set, Tubing, Blood, With and Without Anti-Regurgitation Valve
Trade/Device Name: C-705
Classification Panel: 78 Gastroenterology and Urology
Regulatory Class: Class II
Product Code: 78FJK

Table 1. Product codes in this submission

Product code	Name
955607	AK 98 Dialysis Machine
112062	U9000 Ultrafilter
6430771A	C-705 Accessory Expansion Chamber

PREDICATE DEVICES:

Table 2. Predicate Device(s)

Proposed	Predicates			
Device	**Device**	**510k submitter**	**Predicate 510(k)**	**Clearance Date**
AK 98 Dialysis Machine	Phoenix Hemodialysis Delivery System	Gambro Renal Products	K103832	May 2011
U9000 Ultrafilter	Diaclear Ultrafilter	Gambro Renal Products	K003957	January 2001
C-705 Accessory Expansion Chamber	Single Needle Conversion Kit (Gambro Cartridge Blood Set)	Gambro Renal Products	K070414	October 2007

DESCRIPTION OF THE DEVICES:

The proposed device AK 98 Hemodialysis system, which is subject for this Traditional 510(k) premarket notification, consists of the following:

- AK 98 dialysis machine
- U9000 (Ultrafilter)
- C-705 (Accessory Expansion chamber)

AK 98 Dialysis Machine

AK 98 is a standalone, software controlled hemodialysis machine intended to be used in a chronic care dialysis or hospital care environment for intermittent hemodialysis and/or isolated ultrafiltration treatments of patients with chronic or acute renal failure or fluid overload.

The goal of hemodialysis treatment is to remove waste products and excess fluid from the patient's bloodstream.

The AK 98 is to be used with compatible blood lines, liquid A-concentrate, sodium bicarbonate powder (BiCart) or liquid bicarbonate, Ultrafilter (U9000) and dialyzers (e.g. Revaclear, Polyflux).

The AK 98 pumps blood from the patient into the compatible bloodline, through the dialyzer (where the blood purification takes place), and then back to patient.
The AK 98 handles treatment details, monitors and regulates the pressure and flow on both blood and fluid side, and continually monitors the operation of the dialysis machine.

The AK 98 dialysis machine can be divided into the following parts:

- **Fluid unit -** is used to produce the dialysis fluid (with the correct temperature, flow, and composition) from reverse osmosis water and concentrates (dry or liquid), and to transport the dialysis fluid through the dialyzer. The fluid unit offers Profiling of Ultrafiltration and/or conductivity, it also offers isolated Ultrafiltration. The fluid unit also includes "Clearance Measurement" (Diascan).

  The fluid unit maintains the dialysis fluid flow through the dialyzer and controls ultrafiltration. If a fault occurs, the machine enters a patient safe state, which depending on the fault, can include actions such as bypassing the dialyzer.
- **Blood unit -** is designed to control and supervise the extracorporeal blood circuit. Double needle treatments are most common. Single needle treatments can also be performed with one pump (double clamp function). To prevent coagulation, anticoagulants can be administered by means of the integrated heparin pump. Disposable blood lines are used to transport the blood from the patient to the AK 98 machine and back to the patient.
- **Power supply -** The mains voltage is fed to an AC/DC converter within the AK 98, which generates different DC supplies for the machine.

  Operator's panel - Both the blood unit and the fluid unit are controlled from the operator's panel. The panel contains a touch screen and a number of hard key buttons to the right of the screen. The screen allows the operator to interact with the dialysis machine by pressing various buttons. The hard-key buttons are language independent. The information in the display can be set to different languages.

The Operator's panel (User Interface) lets the Operator set Treatment parameters and Alarm limits (where applicable) and it shows limits and measured values, remaining time for Treatment and Disinfection and other information to the Operator. In an alarm situation, the dialysis machine provides audible and visual indications. Additionally, the visual indication is shown on the alarm light bar on top of the dialysis machine.

It is also possible for a Technician to enter Service mode via the User interface sub-system by use of a PIN code.

Figure 1. Photograph of AK 98 dialysis machine

U9000 Ultrafilter

The Ultrafilter product family (U9000, and its predicate device Diaclear) are ultrafilters intended for water filtration (removal of pyrogens and microorganisms), and filtration of dialysis fluid. The risk of exposure to bacteria and endotoxins can thereby be minimized.

The U9000 is intended to be used in conjunction with an upstream water treatment system. The Ultrafilter U9000 can only be used with Baxter/Gambro/Hospal dialysis

machines equipped with a dedicated U9000 filter holder. This places the U9000 ultrafilter in the pre-dialyzer flow-path to filter the fluid before it reaches the dialyzer.

On the US market, The U9000 is intended to be used as a required component of the AK 98 Hemodialysis System, to minimize the risk of exposure to bacteria and endotoxins by creating a microbiologically high quality dialysate.

C-705 Accessory Expansion Chamber

The C-705 Accessory Expansion Chamber is a single use sterile medical device for hemodialysis intended to be connected to compatible bloodlines for hemodialysis that allow the channeling of blood from the body through its circuits into another device that carries out the hemodialysis effect of the treatment.

C-705 is intended to be used during the delivery of hemodialysis treatment in Single Needle mode; it allows the conversion from Double Needle to Single Needle administration mode of treatments. C705 intended to be used on patients affected by chronic renal failure in an in-center hemodialysis environment. At this time, AK 98 is the only hemodialysis system compatible with the C705 accessory on the US market.

INDICATIONS FOR USE PROPOSED DEVICES:

AK 98 Dialysis Machine

The Baxter AK 98 dialysis machine is intended to be used for intermittent haemodialysis and/or isolated ultrafiltration treatments of patients with chronic or acute renal failure or fluid overload upon prescription by a physician.
The AK 98 dialysis machine is indicated to be used on patients with a body weight of 25 kg or more. The AK 98 dialysis machine is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis or hospital care environment.The Baxter AK 98 dialysis machine is not intended for Selfcare or Home use.

U9000 Ultrafilter

The U9000 Ultrafilter is indicated for purification of incoming water for dialysis fluid as well as purification of dialysis fluid to obtain standard dialysis fluid in accordance with international standards requirements and local regulations. The risk of exposure to bacteria and endotoxins can thereby be minimized. The U9000 Ultrafilter is intended to be used in conjunction with a water treatment system.

C-705 Accessory Expansion Chamber

C-705 Accessory Expansion Chamber is a single use sterile medical device intended to be used during the delivery of Hemodialysis treatment in Single Needle mode, on patients affected by chronic renal failure.

The C-705 Accessory Expansion Chamber is an ancillary device used to allow the conversion from Double Needle to Single Needle administration mode of treatments, after connection to proper Blood Tubing System intended for Haemodialysis treatment in Double Needle mode and to a Dialyzer filter. C-705 Accessory Expansion Chamber shall be used in combination with Blood Tubing System suitable for AK 98 haemodialysis delivery system only. The total extracorporeal blood volume for the extracorporeal circuit including the set, dialyzer, and accessories should represent less than 10% of the patient's blood volume.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

AK 98 Dialysis Machine

The differences between the predicate Phoenix machine and the proposed AK 98 dialysis machine as discussed in the AK 98 Device Comparison Table are considered substantially equivalent. See the comparison in Table 3.

Identification of Predicate Device:

- Trade Name: Phoenix Hemodialysis Delivery System
- 510(k) Holder: Gambro Renal Products
- Common Name: Hemodialysis Delivery System.
- Clearance: K103832 cleared on May 20, 2011.

Identification of Proposed Device:

- Trade Name: AK 98 Dialysis Machine
- 510(k) Holder:: Gambro Lundia AB, Sweden
- Common Name: Hemodialysis Delivery System.
- Clearance: Pending

U9000 Ultrafilter

The differences between the predicate Diaclear Ultrafilter and the proposed device U9000 Ultrafilter as reflected in the Substantial Equivalence (SE) Table are considered substantially equivalent. See the comparison in Table 4.

Identification of Predicate Device

- Trade Name: Diaclear™ Ultrafilter
- 510(k) Submitter/holder: Gambro Industries, Meyzieu Cedex, France.
- Common name: Ultrafilter/Water Purification Subsystem
- Clearance: K003957

Identification of Proposed Device

- Trade Name: U9000 Ultrafilter
- 510(k) Submitter/holder: Baxter Healthcare Corporation
- Common name: Ultrafilter/Water Purification Subsystem
- Clearance: Pending

C-705 Accessory Expansion Chamber

The differences between the predicate Single Needle Conversion Kit and the proposed device C705 Accessory Expansion Chamber as reflected in the Substantial Equivalence (SE) Table are considered substantially equivalent. See the comparison in Table 5.

Identification of Predicate Device

Trade Name: 510(k) Holder:: Common name: Clearance:

Identification of Proposed Device

- Trade Name: C705 Accessory Expansion Chamber
- 510(k) Submitter/holder: Baxter Healthcare Corporation
- Common name: Clearance: Pending

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Table 3. AK 98 Device Comparison

Features	Predicate Device Phoenix 3.40 Cleared under K103832	Proposed Device AK 98 (software version 3.x.x)	Assessment of Differences
Intended use	The Phoenix® Hemodialysis delivery system is intended to be used to provide high flux and flow flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. The device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit.	The Baxter AK 98 dialysis machine is intended to be used for intermittent hemodialysis and/or isolated ultrafiltration treatments of patients with chronic or acute renal failure or fluid overload upon prescription by a physician. The AK 98 dialysis machine is indicated to be used on patients with a body weight of 25 kg or more. The AK 98 dialysis machine is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis or hospital care environment. The Baxter AK 98 dialysis machine is not intended for Selfcare or Home use.	AK 98 can be used with both low and high flux dialyzers for hemodialysis. Performance of the Phoenix and AK 98 machines are equivalent, but the patient weight limit is determined at the system level. Hemofiltration is not supported by AK 98.
Treatment modalities	**Hemodialysis (HD)** - HD DN/SP(Double Needle/Single Pump) treatment - HD SN/SP (Single Needle/Single Pump) treatment **Hemofiltration**	**Hemodialysis** - HD DN/SP treatment - HD SN/SP treatment	Hemofiltration is not supported by AK 98.
Dialysate conductivity monitoring	Yes	Yes	None

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Table 3. AK 98 Device Comparison

Features	Predicate Device Phoenix 3.40 Cleared under K103832	Proposed Device AK 98 (software version 3.x.x)	Assessment of Differences
pH sensor	Yes	No	The AK 98 System controls risk by monitoring the concentrate (pumps' speed. The difference does not impact on safety and effectiveness
Isolated UF	Yes	Yes	None
Ultrafiltration control	Yes	Yes	None
Ultrafiltration supervision	Yes, monitored by TMP (Transmembrane pressure)	Yes, supervision in accordance with IEC 60601-2-16, 4th edition	Both predicate and proposed device supervise Ultrafiltration however due to requirement in IEC 60601-2-16 ed.4; the AK 98 uses separate Ultrafiltration supervision as protection instead of TMP as used by Phoenix. *(subclause 201.12.4.4.103 NET FLUID REMOVAL TMP monitoring is not considered to be an adequate protection against fluid balancing errors in the case of high-flux DIALYSERS.).*
Ultrafiltration accuracy	Between ±35 and ±160 g/h, depending on dialysis fluid flow rate and the ultrafiltration rate. Note: Ultrafiltration accuracy calculated per the Phoenix Operator's Manual a, section 9.2.6 Ultrafiltration system.	Between ±50 and ±100 g/h, depending on ultrafiltration rate. Note: Ultrafiltration accuracy calculated per section 13.1.6 in the AK 98 Operator's Manual	The difference is considered clinically insignificant for low dialysis fluid flow rate. In a worst case scenario the AK 98 has improved accuracycompared to the predicate device. Therefore Baxter considers the ultrafiltration accuracy of the proposed device and the predicate device to be equivalent.
Air detector	Yes	Yes	None
Blood leak detector	Yes	Yes	None

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Table 3. AK 98 Device Comparison

Features	Predicate Device Phoenix 3.40 Cleared under K103832	Proposed Device AK 98 (software version 3.x.x)	Assessment of Differences
Temperature monitoring	Yes	Yes	None
Fail-safe response during power failure	Yes	Yes	None
Prescription profiling	Conductivity profiling (Na)	Conductivity profiling (Na, HCO3)	AK 98 supports profiling of both Na and HCO3.
Disinfection programs	Heat Chemical	Heat Chemical	None
Anti coagulant administration rate:	0/0.5 – 9.9 ml/h	0 – 10.0 ml/h	The range difference is negligible and therefore no impact on safety and effectiveness.
Anti coagulant bolus:	0/0.5 – 10.0 ml	0 – 10.0 ml	The range difference is negligible and therefore no impact on safety and effectiveness.
Blood Flow Rate	10 – 580 ml/min	20 -600 ml/min	The range difference is negligible and therefore no impact on safety and effectiveness.
Blood flow rate accuracy	Accuracy ± 10% if pressure before the pump is not lower (more negative) than – 150 mmHg	For pre-pump pressure range from -200 mmHg to 0 mmHg: ±10 mL/min or ±10% of the set point value, whichever is the largest	The accuracy difference is negligible and therefore no impact on safety and effectiveness.
Dialysate Flow Rate	350 – 800 ml/min	300 – 800 ml/min	The range difference is negligible and therefore no impact on safety and effectiveness.

Table 3. AK 98 Device Comparison

Features	Predicate Device Phoenix 3.40 Cleared under K103832	Proposed Device AK 98 (software version 3.x.x)	Assessment of Differences
Dialysate Flow Rate accuracy	± 5%	±10 % or 50 mL/min whichever is largest	The range difference is negligible and therefore no impact on safety and effectiveness.
Transmembrane Pressure (TMP)	-100 to +450 mmHg (calculated value) ALARM range	-200 - +500 mmHg (calculated value) set of LIMITS	For the proposed device TMP is used for detecting clotting, unlike the predicate device which uses it for Ultrafiltration supervision.
Net Fluid Removal Rate	0 – 4 kg/h	0 – 4 L /h	None
Dialysate Temperature	34 – 39.5 °C	33 – 40 °C	The range difference is negligible and therefore no impact on safety and effectiveness.
Dialysate Conductivity set range	13-17 mS/cm	9-16 mS/cm	The range difference is negligible and therefore no impact on safety and effectiveness.
Arterial pressure	-400 to +150 mmHg	-400 - +300 mmHg	The range difference is not impacting safety and effectiveness. The range can be set by the user.
Venous Pressure	0 to +450 mmHg	+10 – +500 mmHg	The range difference is negligible and therefore no impact on safety and effectiveness.
Blood pressure measurements (BPM)	Yes	Yes	None

Table 3. AK 98 Device Comparison

Features	Predicate Device Phoenix 3.40 Cleared under K103832	Proposed Device AK 98 (software version 3.x.x)	Assessment of Differences
IT connectivity	Yes – Integrates with the EXALIS Dialysis Management Tool	Yes – Integrates with CIS (clinical information system) using HL7 protocol	None

Table 4. U9000 Ultrafilter Device Comparison

Features	Predicate Device – Diaclear Cleared under K003957	Proposed Device U9000 Ultrafilter	Assessment of Differences
Intended Use	The DIACLEAR ultrafilter is intended to be used only with either HOSPAL Integra or Innova or GAMBRO Phoenix dialysis machines equipped with the feature for dialysate filtration.	The Ultrafilter U9000 is intended to be used in conjunction with a water treatment system. WARNING! The Ultrafilter U9000 can only be used with Gambro/Baxter/Hospal dialysis machines equipped with U9000 filter holder.	U9000 is to be used on a new generation of dialysis machines, including AK 98. Diaclear is not compatible with the new system.
Indications for Use	Ultrafiltration with the DIACLEAR ultrafilter is indicated for purification of dialysis fluid to obtain microbiologically high quality dialysis fluid. The risk of exposure to bacteria and endotoxins can thereby be minimised.	The Ultrafilter U9000 is indicated for purification of incoming water for dialysis fluid as well as purification of dialysis fluid to obtain standard dialysis fluid in accordance with international standards requirements and local regulations. The risk of exposure to bacteria and endotoxins can thereby be minimized. The Ultrafilter U9000 is intended to be used in conjunction with a water treatment system	No significant difference
Sterile	Yes	No (Unsterile Device)	The U9000 ultrafilter is produced in a clean room environment, and the bioburden level of the product is

Table 4. U9000 Ultrafilter Device Comparison

Features	Predicate Device – Diaclear Cleared under K003957	Proposed Device U9000 Ultrafilter	Assessment of Differences
			monitored regularly. The product is not sterilized after production. It will be installed in a non-sterile fluid path and after installation, disinfection prior to first use as specified in IFU and OPM is required to be performed by the AK 98 dialysis system. Therefore, the U9000 ultrafilter does not need to be sterile to be substantially equivalent to the predicate device.
Non-Pyrogenic	Yes	No	The U9000 ultrafilter is produced in a clean room environment, and the bioburden level of the product is monitored regularly. The product is not sterilized after production. It will be installed in a non-sterile fluid path and after installation, disinfection prior to first use as specified in IFU and OPM is required to be performed by the AK 98 dialysis system. Therefore, the U9000 ultrafilter does not need to be sterile to be substantially equivalent to the predicate device.
Expiration	3 years	2 years	Design control activities have been conducted and confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness

Table 4. U9000 Ultrafilter Device Comparison

Features	**Predicate Device – Diaclear Cleared under K003957**	**Proposed Device U9000 Ultrafilter**	**Assessment of Differences**
Single Use	No	No	No Difference
Storage conditions	Between 0°C and 30°C	Below 30°C	Design control activities have been conducted and confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness
Pump Compatibility or Electromechanical device compatibility	HOSPAL Integra or Innova or GAMBRO Phoenix dialysis machines	AK 98	The Diaclear and U9000 ultrafilters perform the same function, the only interaction with the electromechanical device is to fit within the holder. The difference does not imply risks to the patient safety or to the treatment effectiveness.

Table 4. U9000 Ultrafilter Device Comparison

Features	Predicate Device – Diaclear Cleared under K003957	Proposed Device U9000 Ultrafilter	Assessment of Differences
Materials	See below	See below	Differences in Materials are deemed not relevant. Each Ultrafilter Device has verified Biocompatibility according to ISO 10993
Membrane	Polyaryylethersulfone (PAES) Polyvinylpyrrolidone (PVP)	Same	Not Applicable
Housing and Header	Polycarbonate (PC)	Same	Not Applicable
Supporting ring	Not Applicable	PolyPropylene (PP)	The predicate device does not have a Supporting ring. Device control activities have been conducted and confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.
Gasket material	Silicon	Same	Not Applicable
Potting material	Polyurethane (PUR)	Same	Not Applicable
Dialysate cap	High Density PolyEthylene (HDPE)	Polypropylene (PP)	. Design control activities have been conducted and confirmed that the different technological characteristics of the new device do not raise different questions of safety and effectiveness.

Table 4. U9000 Ultrafilter Device Comparison

Features	Predicate Device – Diaclear Cleared under K003957	Proposed Device U9000 Ultrafilter	Assessment of Differences
Ultrafiltrate cap	PolyPropylene (PP)	Low Density PolyEthylene (LDPE)	Not Significant
Specifications	See below	See below	Differences in Product Specifications are deemed not relevant. Each Ultrafilter Device is designed and validated to fulfill the System Requirements specific to the therapy system they are used with
Inner diameter of fiber	215 µm	190 µm	Not significant
Wall thickness of fiber	45 µm	Same	Not significant
Efficient surface	1.30 m^2	2.40 m^2	Design control activities have been conducted and confirmed that the different product specifications of the new device do not raise different questions of safety and effectiveness.
Maximum transmembrane pressure	500 mmHg	600 mmHg	Not significant
Operating range: QD	500 – 1000 mL/min	300-1200 mL/min	Not significant

Table 4. U9000 Ultrafilter Device Comparison

Features	**Predicate Device – Diaclear Cleared under K003957**				**Proposed Device U9000 Ultrafilter**					**Assessment of Differences**
Inlet pressure (37°C)	QF (ml/min)	500	750	1000	QF (ml/min)	300	600	900	1200	Not significant
	Pressure (mmHg)	72 ±40%	108 ±40%	144 ±40%	Pressure (mmHg)	59 ±10%	117 ±10%	176 ±10%	235 ±10%	

Table 5. Accessory Comparison

Features	**Predicate Device Single Needle conversion kit (SNK) Cleared under K070414**	**Proposed Device C-705 Accessory Expansion Chamber**	**Assessment of Differences**
Intended Use	The Gambro Cartridge Blood Set is intended for single use in a hemodialysis treatmentusing the Phoenix Dialysis Delivery Systems	C-705 Accessory Expansion Chamber is intended for single use in a hemodialysis treatment.	Different wording but same Intended use
Indications for Use	The Single Needle Conversion Kit is intended for use with the Dialysis Delivery Systems and a Gambro Cartridge Blood Set. When properly used, the kit will allow the clinician to reconfigure a Gambro Cartridge Blood Set to perform a single needle dialysis treatment.	C-705 Accessory Expansion Chamber is a single use sterile medical device intended to be used during the delivery of Hemodialysis treatment in Single Needle mode, on patients affected by chronic renal failure. The C-705 Accessory Expansion Chamber is an ancillary device used to allow the conversion from Double Needle to Single Needle administration mode of treatments, after connection to proper Blood Tubing System intended for	Different wording but same Indications for Use

Table 5. Accessory Comparison

Features	Predicate Device Single Needle conversion kit (SNK) Cleared under K070414	Proposed Device C-705 Accessory Expansion Chamber	Assessment of Differences
		Haemodialysis treatment in Double Needle mode and to a Dialyzer filter. C-705 Accessory Expansion Chamber shall be used in combination with Blood Tubing System suitable for AK 98 haemodialysis delivery system only. The total extracorporeal blood volume for the extracorporeal circuit including the set, dialyzer and accessories should represent less than 10% of the patient's blood volume.	
Target Population	Adult patients with chronic renal failure	patients affected by chronic renal failure	Different wording but same patient population
Sterile	Yes	Yes	No differences
Sterilization Method	Radiation	Ethilene Oxide	Both devices meet sterilization and biocompatibility requirements. The differences in sterilization method does not create different questions of safety or effectiveness,
Expiration	3 years	3 years	No differences
Non-Pyrogenic	Yes	Yes	No differences
Single Use	Yes	Yes	No differences
Pump Compatibility or Electromechanical device compatibility	Phoenix and Centrysystem 3	AK 98	The accessory is used on different dialysis delivery systems. Two accessories perform the same function, the only interaction with the electromechanical device is to fit

Table 5. Accessory Comparison

Features	Predicate Device Single Needle conversion kit (SNK) Cleared under K070414	Proposed Device C-705 Accessory Expansion Chamber	Assessment of Differences
			within the holder. The difference does not imply risks to the patient safety or to the treatment effectiveness.
Materials			
Tubing (direct contact with blood for transport tubes and indirect contact for service tube)	PVC	PVC	The PVC matieral is tested for biocompatibility and performance in accordance with FDA guidance. No significance to safety or effectiveness
Dialyzer Connector Blue (inner Part)	PVC	PVC	No differences
Male Locking Dialyzer Connector BlueA	M-ABS	M-ABS	No differences
Expansion Chamber	PETG	PVC	Rigid PVC-based material is suitable for the component function and tested for biocompatibility
Female luer connector (indirect contact with blood)	PETG	PETG	No differences
Clamps	Pinch	Pinch	No differences
Blood Tubing Length	Dialyzer Length (venous) :46 cm Dialyzer Length (arterials) :51 cm	Dialyzer Length (venous) :75 cm Dialyzer Length (arterials) :8 cm	The accessory is used on different dialysis delivery systems. The difference does not imply risks to the patient safety or to the treatment effectiveness.

Table 5. Accessory Comparison

Features	Predicate Device Single Needle conversion kit (SNK) Cleared under K070414	Proposed Device C-705 Accessory Expansion Chamber	Assessment of Differences
Blood Pathway	ID: 4.17 mm OD: 6.50 mm	ID: 4.30 mm OD: 6.80 mm	The accessory is used on different dialysis delivery systems. The difference does not imply risks for patient safety nor treatment effectiveness.
Connection to dialyzer	ID: 4.17 mm OD: 6.80 mm	ID: 4.30 mm OD: 6.6 mm	The accessory is used on different dialysis delivery systems. The difference does not imply risks for the patient safety nor treatment effectiveness.
Priming Volume	45 ml	50 ml	C-705 Accessory Expansion Chamber has one expansion chamber to be connected after the dialyzer filter while Cartridge Single Needle Conversion Kit has two smaller expansion chambers to be connected before and after the dialyzer filter . Consequence of this difference is a higher priming volume of the proposed device (50 ml) compared to the priming volume of the predicate device (45 ml).
Packaging	Blister	Blister	No differences

DISCUSSION OF NONCLINICAL TESTS:

AK 98 Dialysis Machine

Performance testing in accordance with FDA guidance document Guidance for the Content of Premarket Notifications for Hemodialysis Systems was conducted on the AK 98 dialysis machine to evaluate the functional performance of the system. The performance testing confirms AK 98 remain as safe and effective as Phoenix dialysis system and is substantially equivalent.

In summary the AK 98 has successfully implemented performance requirements and subsequent outputs verifying and validating:

- Functional testing demonstrating the AK 98 dialysis machine and its accessories performs as designed and expected.
- The device complies with the latest edition of IEC60601-2-16. Testing was confirmed by TÜV SÜD recognized test laboratory as part of the testing of IEC60601-1 edition 3.1. The testing confirmed the device meets the requirements for Essential Performance according to the particular standard IEC60601-2-16.
- Electrical safety testing according to latest edition of IEC60601-1. The standard includes reports for software, alarms, usability, safety and performance.
- Electromagnetic compatibility compliance in accordance with IEC 60601-1-2:2014.
- Risk assessment and Risk Control Measures. A therapy level, product level and process level hazard analysis confirms the device does not perform in an unexpted or unsafe manner.
- Labeling, software including Cybersecurity, Human Factors requirements have been successfully implemented.
- Biocompatibility testing was performed in accordance with ISO 10993-1.

U9000 Ultrafilter

Performance testing in accordance with FDA guidance document Guidance for Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis was performed on the U9000 Ultrafilter. The performance testing confirms that the device is safe, effective and is substantially equivalent to the predicate device when used in accordance with the instructions for use.

The following performance testing was conducted to verify the performance of the proposed device:

- Biocompatibility,
- Pressure drop
- Retention capacity for Bacteria and Endotoxin.
- Ultrafiltration rate
- Dilaysis fluid composition
- Filter and membrane integrity
- Chemical evaluation

The specifications of the U9000 ultrafilter are provided in accordance with FDA Guidance.

C-705 Accessory Expansion Chamber

Performance testing in accordance with FDA guidance document Guidance Hemodialysis Tubing Sets- Premarket Notification [510(k)] Submission, was performed on the C-705 Accessory Expansion Chamber indicates that the device is safe, effective and substantially equivalent to the predicate device, when used in accordance with the instructions for use.

The following performance testing were conducted to verify the performance of the proposed device configurations:

- Biocompatibility testing,
- Clamp Performance,
- Tensile Strength of Connections,
- Priming Volume
- Filling of Expansion Chamber,
- Connector Performance,
- Structural Integrity testing,
- Fitting Test,
- Mechanical Hemolysis test.

The specifications, and functionality of components are provided accordance with FDA Guidance