October 19, 2021

Baxter Healthcare Corporation
Carina Pforr
Regulatory Affairs Specialist
25212 W. Illinois Route 120
Round Lake, Illinois 60073

Re: K211035
Trade/Device Name: U9000 Plus Ultrafilter
Regulation Number: 21 CFR 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: September 10, 2021
Received: September 17, 2021

Dear Carina Pforr:

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,

Glenn B Bell, Ph.D.
Director
THT3A1: Renal, Gastrointestinal,
Obesity and Transplantation 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)*
K211035

Device Name
U9000 Plus Ultrafilter

Indications for Use *(Describe)*
The U9000 Plus 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 Plus Ultrafilter is intended to be used in conjunction with a water treatment system.

WARNING! The U9000 Plus Ultrafilter can only be used with AK98 dialysis machines equipped with holder for an ultrafilter.

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

Submission Date: 05 April 2021

## OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

## CONTACT PERSON:

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## IDENTIFICATION OF THE DEVICE:

**Common Name:** Ultrafilter/Water Purification Subsystem
**Trade/Device Name:** U9000 Plus Ultrafilter
**Classification Panel:** 78 Gastroenterology and Urology
**Regulation Number:** 21 CFR 876.5665
**Regulation Name:** Water purification system for hemodialysis
**Regulatory Class:** Class II
**Product Code:** FIP

### Table 1. Product codes in this submission

| Product code | Name |
|---|---|
| 955825 | U9000 Plus Ultrafilter |

## PREDICATE DEVICE:

### Table 2. Predicate Device

| Device | Company | Predicate 510(k) | Clearance Date |
|---|---|---|---|
| U9000 Ultrafilter | Gambro Dialysatoren GmbH | K201809 | March 2020 |

## DESCRIPTION OF THE DEVICE:

The Ultrafilter product family (U9000 Plus, and its predicate device U9000) 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 Plus is intended to be used in conjunction with an upstream water treatment system. The Ultrafilter U9000 Plus can only be used with AK98 machines equipped with a dedicated holder. This places the U9000 Plus ultrafilter in the pre-dialyzer flow-path to filter the fluid before it reaches the dialyzer.

U9000 Plus Ultrafilter 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.

After installation, U9000 Plus Ultrafilter becomes an integral part of the dialysis fluid flow path of the dialysis machine; all machine processes that involve the Ultrafilter (e.g., dialysis fluid preparation, disinfection, rinsing) are controlled by the dialysis machine.

## INDICATIONS FOR USE OF PROPOSED DEVICE:

The U9000 Plus 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 Plus Ultrafilter is intended to be used in conjunction with a water treatment system.

WARNING! The U9000 Plus Ultrafilter can only be used with AK98 dialysis machines equipped with holder for an ultrafilter.

## TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The differences between the predicate U9000 Ultrafilter and the proposed device U9000 Plus Ultrafilter as reflected in the Substantial Equivalence (SE) Table are considered substantially equivalent. See the comparison in Table 3.

### Identification of Predicate Device

Trade Name: U9000 Ultrafilter
510(k) Submitter/holder: Baxter Healthcare Corporation
Common name: Ultrafilter
Clearance: K201809

## Identification of Proposed Device

Trade Name: U9000 Plus Ultrafilter
510(k) Submitter/holder: Baxter Healthcare Corporation
Common name: Ultrafilter
Clearance: Pending

## Table 3. Device Comparison

| Features | Predicate Device<br>U9000 Ultrafilter<br>Cleared under K201809 | Proposed Device<br>U9000 Plus Ultrafilter | Assessment of Differences |
|---|---|---|---|
| Intended Use | The U9000 Ultrafilter is intended to be used in conjunction with a water treatment system.<br>WARNING! The U9000 Ultrafilter can only be used with AK98 dialysis machines equipped with U9000 filter holder. | The U9000 Plus Ultrafilter is intended to be used in conjunction with a water treatment system.<br>WARNING! The U9000 Plus Ultrafilter can only be used with AK98 dialysis machines equipped with holder for ultrafilter. | No significant difference |
| Indications for Use | 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 Plus 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. | No significant difference |
| Sterile | No<br>(Unsterile Device) | Same | Not applicable |
| Non-Pyrogenic | No | Same | Not applicable |
| Expiration | 2 years | Same | Not applicable |
| Single Use | No | Same | Not applicable |
| Storage Conditions | Below 30°C (86°F) | Same | Not applicable |
| Pump Compatibility or Electromechanical device compatibility | AK98 | Same | Not applicable |

| **Materials** | | | Each Ultrafilter Device has verified Biocompatibility according to ISO 10993 |
|---|---|---|---|
| Membrane | Polyarylethersulfone (PAES)<br>Polyvinylpyrrolidone (PVP) | Same | Not applicable |
| Housing<br>Header<br>Plug | Polycarbonate (PC) | Polyphenylsulfone (PPSU) | Material is in indirect contact with blood (contact with fluid)<br>Biocompatiblity of changed material has been verified according to ISO 10993 |
| Supporting ring | Polypropylene (PP) | Same | Not applicable |
| Gasket material | Silicone rubber (SIR) | Same | Not applicable |
| Potting material | Polyurethane (PUR) | Same | Not applicable |
| Filtrate Protection cap | Low Density Polyethylene (LDPE) | Same | Not applicable |
| Protection cap | Polypropylene (PP) | Same | Not applicable |

| **Specification** | | | No difference<br>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 | 190 µm ± 10 µm | Same | Not applicable |
| Wall thickness of fiber | 45 µm ± 3 µm | Same | Not applicable |
| Effective surface area | 2.40 m² | Same | Not applicable |
| Maximum transmembrane pressure | 600 (mmHg) | Same | Not applicable |

| Operating range: QD | | 300-1200 mL/min | | | | Same | | | | Not applicable |
|---|---|---|---|---|---|---|---|---|---|---|
| Inlet pressure (37°C) | QF (ml/min) | 300 | 600 | 900 | 1200 | 300 | 600 | 900 | 1200 | Not applicable |
| | Pressure (mmHg) ±10% | 59 | 117 | 176 | 235 | Same | Same | Same | Same | Not applicable |

## DISCUSSION OF NONCLINICAL TESTS:

### U9000 Plus 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 Plus 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
- Dialysis fluid composition
- Filter and membrane integrity
- Chemical evaluation

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