August 1, 2025

Vantive US Healthcare LLC
Kristen Bozzelli
Senior Manager, Regulatory Affairs
One Baxter Parkway, Building 6
Deerfield, IL 60015

Re: K250508
Trade/Device Name: AK 98 Dialysis Machine (955607)
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: July 3, 2025
Received: July 3, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Maura Rooney
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250508

Device Name

AK 98 Dialysis Machine (955607)

Indications for Use *(Describe)*

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.

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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510(k) Summary

July 30, 2025

OWNER:

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CONTACT PERSON:

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Senior Manager, Regulatory Affairs
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IDENTIFICATION OF THE DEVICE:

Common Name: Hemodialysis Delivery System
Trade/Device Name: AK 98 Dialysis Machine (955607)
Classification Panel: Gastroenterology and Urology
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI

Table 1. Product Codes in this Submission

Product Code	Name
955607	AK 98 Dialysis Machine

PREDICATE DEVICE:

Table 2. Predicate Device

Proposed	Predicate			
Device	**Device**	**510(k) Submitter**	**Predicate 510(k)**	**Clearance Date**
AK 98 Dialysis Machine	AK 98 Dialysis Machine	Baxter Healthcare Corporation	K232467	September 14, 2023

DESCRIPTION OF THE DEVICE:

The AK 98 Dialysis Machine is a standalone hemodialysis machine intended for use as a single patient dialysis machine to perform HD treatments of patients with renal failure or fluid overload. The Vantive AK 98 Dialysis Machine is intended to be used in a chronic dialysis or hospitale care environment 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 intended to be used on patients with a body weight of 25 kg or more.

To perform hemodialysis therapy, the AK 98 system needs a high purity water source and the appropriate consumables for treatment, including but not limited to: cleaning products, ultrafilters, acid and base dialysate concentrates, bloodlines, and dialyzers.

In hemodialysis therapies, the AK 98 is used to pump the blood through the extracorporeal circuit and to monitor the arterial and venous pressure, but the blood directly contacts only the disposable bloodline and dialyzer, not the monitor itself.

The fluid unit of the AK 98 Dialysis Machine 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 upon the fault, can include actions such as bypassing the dialyzer.

The fluid path of the AK 98 is composed of a variety of different materials, including silicone tubing.

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INDICATIONS FOR USE PROPOSED DEVICE:

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.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The differences between the predicate AK 98 dialysis 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.

Table 3. AK 98 Device Comparison

Features	Predicate Device Cleared under K232467	Proposed Device AK 98 Hemodialysis System	Assessment of Differences
Intended Use/ Indications for Use	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.	Same	Not Applicable
Treatment modalities	**Hemodialysis** - HD DN/SP treatment - HD SN/SP treatment	Same	Not Applicable
Dialysate conductivity monitoring	Yes	Same	Not Applicable
Isolated UF	Yes	Same	Not Applicable
Ultrafiltration Control	Yes	Same	Not Applicable
Ultrafiltration Supervision	Yes, supervision in accordance with IEC 60601-2-16, 4th edition	Same	Not Applicable
Ultrafiltration accuracy	Between ±50 and ±100 g/h, depending on ultrafiltration rate	Same	Not Applicable

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Table 3. AK 98 Device Comparison

Features	Predicate Device Cleared under K232467	Proposed Device AK 98 Hemodialysis System	Assessment of Differences
	Note: Ultrafiltration accuracy calculated per section 13.1.6 in the AK 98 Operator's Manual Ultrafiltration control: 50 mL or ± 50 mL/h x passed or treatment time (h) or ± 2.5% of the accumulated UF volume, whichever is largest Provided the highest set UF rate (4 L/h), the worst-case accuracy is 100 g/h (based on ± 2.5% of the accumulated UF volume).		
Air detector	Yes	Same	Not Applicable
Blood leak detector	Yes	Same	Not Applicable
Temperature monitoring	Yes	Same	Not Applicable
Fail-safe response during power failure	Yes	Same	Not Applicable
Prescription profiling	Conductivity profiling (Na, HCO_3)	Same	Not Applicable
Disinfection programs	Heat Chemical	Same	Not Applicable
Anti coagulant administration rate	0 – 10.0 ml/h	Same	Not Applicable
Anti coagulant bolus	0 – 10.0 ml	Same	Not Applicable
Blood flow rate	20 – 600 ml/min	Same	Not Applicable

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Table 3. AK 98 Device Comparison

Features	Predicate Device Cleared under K232467	Proposed Device AK 98 Hemodialysis System	Assessment of Differences
Blood flow rate accuracy	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	Same	Not Applicable
Dialysate flow rate	300 – 800 ml/min	Same	Not Applicable
Dialysate flow rate accuracy	±10% or 50 ml/min whichever is largest	Same	Not Applicable
Transmembrane pressure	-200 – +500 mmHg (calculated value) set of LIMITS	Same	Not Applicable
Net fluid removal rate	0 – 4 L/h	Same	Not Applicable
Dialysate temperature	33 – 40 °C	Same	Not Applicable
Dialysate conductivity set range	9 – 16 mS/cm	Same	Not Applicable
Arterial pressure	-400 - +300 mmHg	Same	Not Applicable
Venous pressure	+10 - +500 mmHg	Same	Not Applicable
Blood pressure measurements (BPM)	Yes	Same	Not Applicable
IT connectivity	Yes Integrates with CIS (clinical information system) using HL7 protocol	Same	Not Applicable
Silicone Tubing	Peroxide-cured and Platinum-cured tubing	Platinum-cured tubing	Performance, biocompatibility, and extractables testing demonstrates that the difference in the curing process does not impact the performance or safety of the AK 98 Hemodialysis System

DISCUSSION OF NONCLINICAL TESTS:

Functional performance testing, biocompatibility testing, and extractables and leachables assessment was conducted on the AK 98 dialysis machine with the proposed platinum-cured silicone tubing. This testing confirms that the AK 98 dialysis machine remains as safe and effective as the predicate AK 98 dialysis machine and is substantially equivalent.