July 12, 2024

Deka Research and Development
Paul Smolenski
Regulatory Affairs
340 Commercial Street
Manchester, NH 03101

Re: K233557
Trade/Device Name: HemoCare® Hemodialysis System
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, FIP, FJK
Dated: June 12, 2024
Received: June 13, 2024

Dear Paul Smolenski:

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.

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,

Maura Rooney -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)*

K233557

Device Name

HemoCare® Hemodialysis System

Indications for Use *(Describe)*

The HemoCare® Hemodialysis System is indicated for hemodialysis treatment, including short daily and nocturnal hemodialysis, of renal failure patients. The HemoCare Hemodialysis System is indicated for use in chronic dialysis facilities, self-care dialysis facilities, and the home setting. All treatments must be prescribed by a physician and administered by a trained operator. Treatments must be performed with the assistance or observation of an individual who has been trained and is considered competent in the use of the device. The HemoCare Hemodialysis System is not indicated for solo hemodialysis in the home setting.

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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510(k) Summary

This 510(k) Summary of Safety and Effectiveness information is prepared in accordance with the requirements of 21 CFR Part 807.92.

1 Submitter

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Date Prepared:	June 6, 2024

2 Device

Trade Name:	HemoCare® Hemodialysis System
Common Name:	Hemodialysis delivery system
Classification Regulation:	21 CFR § 876.5860 - High Permeability Hemodialysis System 21 CFR § 876.5665 - Water Purification System for Hemodialysis 21 CFR § 876.5820 - Hemodialysis System and Accessories
Product Codes:	KDI, FIP, FJK
Regulatory Class:	Class II

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3 Predicate Device

Predicate Device comparisons were made to the following four devices:

- Aksys PHD (K010131, cleared on March 26, 2002) is indicated for the same therapy, the same user population and in the same use environments. The Aksys PHD establishes predicate features, including dialysate proportioning (self-priming and delivery), online replacement fluid generation for bolus delivery, blood flow control, ultrafiltration, reusable blood treatment set, and automatic post-treatment device disinfection.
- Nephros HDF Assist Module (K210575, cleared May 13, 2022) provides a predicate device that performs online generation of substitution fluid from commercially available (510(k) cleared) chemical concentrates.
- NxStage System One (K141752, cleared 12/19/2014) provides a predicate device that has the same home, nocturnal hemodialysis indication.
- Outset Tablo (K211370, cleared July 29, 2022) provides a predicate device since it features integrated water purification, and two-way wireless data transfer with its cloud, like the HemoCare Hemodialysis System.

4 Device Description

The HemoCare® Hemodialysis System is a self-contained, software-controlled device that provides hemodialysis treatments, including short daily and nocturnal hemodialysis, for patients with renal failure. The device is intended for use by a single patient in chronic dialysis facilities, self-care dialysis facilities, and the home setting. The HemoCare® Hemodialysis System is composed of the following components:

- The HemoCare® Treatment Device is a hemodialysis delivery system. When provided a source of water for dialysis, it produces infusion grade dialysate using liquid acid and powder bicarbonate concentrates. The Treatment Device provides secure, 2-way communication with the cloud for transmitting patient registration, physician-prescribed dialysis treatments, patient monitoring, and device status information.
- The HemoCare® Water Device is a water purification system that produces water for dialysis through distillation of EPA drinking water. The Water Device interfaces with the Treatment Device.
- The Blood Treatment Set connects to the patient access site and interfaces with the Treatment Device to provide extracorporeal blood flow through a dialyzer for dialysis treatment. The Blood Treatment Set is terminally sterilized and includes displacement blood pumps, a heparin delivery system, and an access disconnect sensor. The Blood Treatment set can be used for up to 16 treatments.

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The following accessories are for use with the HemoCare® System:

- Centrisol Acid Concentrate (45x)
- Optiflux® F200 NR Dialyzer
- HemoCare Bicarbonate Concentrate Set

Conventional dialysis treatment supplies are also needed to perform dialysis treatments (e.g. gloves, alcohol swabs, chlorine test strips, access needles, scale, blood pressure cuff, etc.)

5 Indications for Use

The HemoCare® Hemodialysis System is indicated for hemodialysis treatment, including short daily and nocturnal hemodialysis, of renal failure patients. The HemoCare® Hemodialysis System is indicated for use in chronic dialysis facilities, self-care dialysis facilities, and the home setting. All treatments must be prescribed by a physician and administered by a trained operator. Treatments must be performed with the assistance or observation of an individual who has been trained and is considered competent in the use of the device. The HemoCare® Hemodialysis System is not indicated for solo hemodialysis in the home setting.

6 Substantial Equivalence Discussion

6.1 Comparison of Intended Use and Indications for Use

Table 1. Comparison of Intended Use and Indications for Use

	Subject Device (HemoCare® Hemodialysis System)	**Predicate Device (Aksys PHD, K210575)**	**NxStage System One (K141752)**	**Comparison**
Intended Use	Intended to deliver high permeability hemodialysis therapy to patients with renal failure	Intended to deliver high permeability hemodialysis therapy to patients with renal failure	Intended to deliver high permeability hemodialysis therapy to patients with renal failure	Same
Prescription Use	Yes	Yes	Yes	Same
Intended Population	Renal failure patients	Renal failure patients	Renal failure patients	Same
Use Environment	Clinical care facilities and home use	Clinical care facilities and home use	Clinical care facilities and home use	Same
Operator Training	Operator training required	Operator training required	Operator training required	Same

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	Subject Device (HemoCare® Hemodialysis System)	Predicate Device (Aksys PHD, K210575)	NxStage System One (K141752)	Comparison
Nocturnal Use	Yes	No	Yes	The NxStage System One Predicate Device is indicated for home, nocturnal hemodialysis.

6.2 Comparison of Technical Characteristics

A summary of the technological similarities and differences between the Subject and Predicate Devices is provided in the following tables.

Table 2. SE Comparison with Aksys PHD

	Subject Device (HemoCare® Hemodialysis System)	Predicate Device (Aksys PHD, K210575)	Comparison
Product Codes	KDI	KDI	Same
Dialysis Delivery System	Conventional, high permeability dialysis with or without ultrafiltration	Conventional, high permeability dialysis with or without ultrafiltration	Same
User Interface	Digital Touchscreen	Digital Touchscreen	Same
Software controlled	Yes	Yes	Same
Dialysate production	Yes, proportioning of standard acid and bicarbonate chemical concentrates (45x) and purified water	Yes, proportioning of standard acid and bicarbonate chemical concentrates (45x) and purified water	Same
Substitution fluid	Online prepared infusion quality dialysate used for priming extracorporeal circuit, bolus infusions, and rinseback	Online prepared infusion quality dialysate used for priming extracorporeal circuit, bolus infusions, and rinseback	Same. The Nephros HDF Assist Module Predicate Device produces online substitution fluid for infusion from commercially available chemical concentrates.
Blood Tubing Set Compatibility	Device-specific blood tubing set	Device-specific blood tubing set	Same

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	Subject Device (HemoCare® Hemodialysis System)	Predicate Device (Aksys PHD, K210575)	Comparison
Blood pump	Diaphragm pump	Peristaltic/Rotary Pump	Substantially Equivalent. Both pumps produce the same maximum blood flow rates and both pumps are bio- and hemocompatible, as defined by ISO 10993-1.
Patient Access Compatibility	A/V fistula or central venous catheter	A/V fistula or central venous catheter	Same
Safety Features	• Alarms and Alerts • Air detection • Blood pressure monitor • Blood leak detection • Tube Clamps • Blood flow occluder • Conductivity and temperature monitoring • Access Disconnect Monitoring	• Alarms and Alerts • Air detection • Blood pressure monitor • Blood leak detection • Tube Clamps • Blood flow occluder • Conductivity and temperature monitoring	Substantially Equivalent. Subject Device's additional safety feature does not change the hemodialysis therapy or limit the use of the device within the intended population.
Material Biocompatibility	ISO 10993-1	ISO 10993-1	Same
Standards Compliance	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-1-8 • IEC 60601-1-11 • IEC 60601-2-16 • AIM 7351731	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-4 • IEC 60601-2-5 • IEC 60601-2-16 • IEC 60601-2-30	Substantially Equivalent Both systems meet applicable standards.

Table 3. SE Comparison with Nephros HDF Assist Module

Characteristic	HemoCare Hemodialysis System (Subject Device)	Nephros HDF Assist Module (Predicate Device)	Comparison
Product Code	KDI	KDI	Same
Regulation Number	876.5860	876.5860	Same
Intended Use	Deliver high permeability hemodialysis therapy to patients with renal failure	Deliver high permeability hemodialysis therapy to patients with renal failure	Same
Prescription Use	Yes	Yes	Same

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Characteristic	HemoCare Hemodialysis System (Subject Device)	Nephros HDF Assist Module (Predicate Device)	Comparison
Online generation of replacement fluid	Yes	Yes	Same
Chemical Concentrates	510(k) cleared acid and bicarbonate concentrates	510(k) cleared acid and bicarbonate concentrates	Same

Table 4. SE Comparison with Outset Tablo Hemodialysis System

	Subject Device (HemoCare® Hemodialysis System)	Predicate Device (Tablo Hemodialysis System, K211370)	Comparison
Product Codes	KDI	KDI	Same
Dialysis Delivery System	Conventional, high permeability dialysis with or without ultrafiltration	Conventional, high permeability dialysis with or without ultrafiltration	Same
2-way cloud communication	Yes	Yes	Same
Blood Tubing Set Use Life	Up to 16 treatments	1 treatment	Substantially Equivalent. Clinical testing, verification bench testing, and cleaning validation have demonstrated that use of the blood tubing up to 16 uses is safe and effective.
Dialyzer	High permeability, commercially available, single use	High permeability, commercially available, single use	Same
Extracorporeal volume (without dialyzer)	116.5 mL	140 mL	Substantially equivalent. The Subject Device's smaller volume results in less blood loss compared to the Predicate Device's if blood cannot be returned.
Blood returned following power loss	Yes	Yes	Same
Disinfection method	Heat and chemical disinfection	Heat and chemical disinfection	Same

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	Subject Device (HemoCare® Hemodialysis System)	Predicate Device (Tablo Hemodialysis System, K211370)	Comparison
Water Purification Mechanism	Vapor Compression Distillation	Reverse Osmosis	Substantially equivalent. Both devices produce water for dialysis that meets the quality standards specified in ISO 23500-3.
Chlorine/Chloramine removal	Carbon Filter	Carbon Filter	Same
Water Device Source Water Quality	EPA Drinking Water	EPA Drinking Water	Same
Water Device Product Water Quality	ISO 23000-3 Water for Dialysis	ISO 23000-3 Water for Dialysis	Same
Safety Features	• Alarms and Alerts • Air detection • Blood pressure monitor • Blood leak detection • Tube Clamps • Blood flow occluder • Conductivity and temperature monitoring • Access Disconnect Monitoring	• Alarms and Alerts • Air detection • Blood pressure monitor • Blood leak detection • Tube Clamps • Blood flow occluder • Conductivity and temperature monitoring	Substantially Equivalent. Additional safety feature does not change the hemodialysis therapy or limit the use of the device within the intended population.
Material Biocompatibility	ISO 10993-1	ISO 10993-1	Same
Standards Compliance	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-1-8 • IEC 60601-1-11 • IEC 60601-2-16 • AIM 7351731	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-1-8 • IEC 60601-1-11 • IEC 60601-2-16 • AIM 7351731	Same

7 Performance Data

The following performance data were provided to support the substantial equivalence determination:

Biocompatibility Testing

Biocompatibility testing was performed in accordance with ISO 10993-1:2018 and FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and

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testing within a risk management process" (2023). The following endpoints were evaluated to support the biological safety of the HemoCare® System:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Subacute, Subchronic and Chronic System Toxicity
- Pyrogenicity
- Genotoxicity
- Hemocompatibility
- Carcinogenicity
- Chemical Characterization
- Toxicological Risk Assessment

Electrical Safety and Electromagnetic Compatibility

Testing to support electrical safety and EMC was conducted in compliance with FDA Guidance, Electromagnetic Compatibility (EMC) of Medical Devices (2022), and the following standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-1-8
- IEC 60601-1-11
- IEC 60601-2-16
- AIM 7351731

Software Verification and Validation Testing

Software verification and validation testing was performed in compliance with IEC 62304. Testing results demonstrate that the device meets all software performance requirements.

Bench Performance Testing

Benchtop verification testing was performed to verify specified performance across the following areas:

- Alarm and Alerts
- Safety Systems
- Dialysate Quality and Flow
- Ultrafiltration Accuracy
- Water Quality
- Microbiological Safety
- Blood Flow
- Heparin Delivery
- System Disinfection
- Storage and Distribution

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Sterilization and Shelf Life

Testing was performed in compliance with ISO 11137-1 (2018), ISO 11137-2 (2013), ISO 11737-1 (2021), ISO 11737-2 (2019), ANSI/AAMI ST72:2019, and ISO 11607-1:2019 to demonstrate the blood treatment set is properly sterilized for its labeled shelf life.

Human Factors

Human Factors validation testing was performed according to the FDA Guidance, Applying Human Factors and Usability Engineering to Medical Devices (2016), and in compliance with ISO 62366 (2020). Testing demonstrated that the HemoCare® System's user interface supports safe and effective use for its intended users, uses, and use environments.

Clinical Testing

A prospective, multi-center, open label, cross-over study was performed to evaluate the safety and efficacy of the HemoCare® System during home use without the assistance of trained medical professionals. The study's primary endpoints for safety and efficacy were met.

8 Conclusion

The results of clinical and non-clinical testing demonstrate that the HemoCare® Hemodialysis System meets all performance specifications and is safe and effective. The HemoCare® System does not raise any new or different questions of safety or effectiveness. The HemoCare® System is substantially equivalent to the Predicate Devices.