November 14, 2025

Fresenius Medical Care Renal Therapies Group, LLC
Greg Calder
Senior Director, Regulatory Project Management & Operations
920 Winter Street
Waltham, MA 02451

Re: K250471
Trade/Device Name: AquaC UNO H
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System For Hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: October 14, 2025
Received: October 14, 2025

Dear Greg Calder:

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,

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)*

K250471

Device Name

AquaC UNO H

Indications for Use *(Describe)*

The AquaC UNO H Portable Water Purification System is a reverse osmosis unit intended for use with hemodialysis systems to remove organic and inorganic substances and microbial contaminants from the water used for treating hemodialysis patients or related therapies.

The AquaC UNO H can be connected to hemodialysis equipment used in hospitals, clinics and in home environments. This device is intended to be a component in a complete water purification system, and is not a complete water treatment system. The reverse osmosis unit must be preceded by pre-treatment devices, and may need to be followed by post-treatment devices as well, to meet current AAMI/ANSI and FDA recognized U.S. standards.

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.

1. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92

1.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
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Contact Person:	Greg Calder, Senior Director Regulatory Affairs - Devices
Preparation Date:	14 February 2025

1.2. Device Name

Trade Name:	AquaC UNO H
Common Name:	Subsystem, Water Purification
Regulation Name:	Water purification system for hemodialysis
Regulatory Class:	Class II per 21 CFR § 876.5665
Product Code:	FIP
Product Code Name:	Subsystem, Water Purification
FDA Review Panel:	Gastroenterology/Urology

1.3. Legally Marked Predicate Device

The legally marketed predicate device is the AquaC UNO H cleared under K143617.

1.4. Device Description

The AquaC UNO H water purification system is a microcontroller-controlled, fully automatic reverse osmosis (RO) system with heat disinfection function, which uses pretreated soft water (hereinafter referred to as "feed water") to produce highly deionized water (hereinafter referred to as "dialysis water") for use by a hemodialysis (HD) device and preparation of dialysis concentrates.

Feed water is defined as the water supplied to a water treatment system or an individual component of a water treatment system per *ISO 23500-1:2019 Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements*. The feed water must be of drinking water standard, filtered, free of iron and chlorine, and softened. Potentially critical limits must be monitored by regular checks. Bacterial growth in the system must be prevented by continuous operation of the system with a minimum of idle times and by preventive measures such as chemical or heat disinfection.

The dialysis water flows through the heater, across the dialysis water conductivity/temperature sensor and the dialysis water stop valve or outlet into the ring main. The ring main can be connected to a HD

device or to a device used for the preparation of dialysis concentrates. Excess dialysis water flows through the check valve and back into the break tank. The concentrate flows through the concentrate drain restrictor and is either returned into the break tank or drained via the drain valve.

The system features the following operating modes:

- Standby
- Supply
- Rinse
- Module Heat Disinfection
- Ring Disinfection
- Chemical Disinfection
- Decalcification
- Isolated Standby

1.4.1 Materials of Use

AquaC UNO H is classified as externally communicating, blood path indirect, long-term exposure (> 30 days) duration Category C device in accordance with FDA guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (04 September 2020).

Materials in contact with feed water are detailed in Table 1. Materials in contact with dialysis water are detailed in Table 2.

Table 1: Materials in Contact with Feed Water

Material	Application
Polypropylene (PP)	Main water contact, actor-/sensor-blocks, break tank
Stainless steel 1.4571	Pipes, cylinder bolts, springs
Stainless steel 1.4404	Pressure transducer, conductivity cell
Platinum cross-linked silicone	Tubing
Ethylene propylene diene monomer (EPDM)	Sealings, all O-rings, valve membranes
Fluoroelastomer (Viton) (FKM)	Valve membrane
Fluorinated ethylene propylene (FEP)	Tubing
Polyvinylidene fluoride (PVDF)	Plate within check valve
Noryl GTX 810/950	Cage for valves
Polybutylene terephthalate (PBT)	Housing flow meter
Polyvinyl chloride (PVC)	Hose connection
Titan	Temperature sensor

Table 2: Materials in Contact with Dialysis Water

Material	Application
PP	Main water contact / actor-/sensor blocks
Stainless steel 1.4571	Pipes, cylinder bolts, springs
Stainless steel 1.4404	Pressure transducer, conductivity cell
Platinum cross-linked silicone	Tubing
Polysulfone (PSU)	Dialysis water collector tube within the RO membrane
Polyethylene (PE)	Dialysis water tube from membranes to hydraulic unit
EPDM	Sealings, all O-rings
PVDF	Plate within check valve
Ceramics Al_2O_3	Pressure transducer
Noryl GTX 810/950	Cage for valves
Titan	Temperature sensor
PBT 35%GF	Flowmeter

1.5. Intended Use

The intended use of the reverse osmosis device is to remove organic and inorganic ions and microbiological contaminants from the feed water to fulfill the requirements of ISO 13959 'water for haemodialysis and related therapies'.

1.6 Indications for Use

The AquaC UNO H Portable Water Purification System is a reverse osmosis unit intended for use with hemodialysis systems to remove organic and inorganic substances and microbial contaminants from the water used for treating hemodialysis patients or related therapies.

The AquaC UNO H can be connected to hemodialysis equipment used in hospitals, clinics and in home environments. This device is intended to be a component in a complete water purification system, and is not a complete water treatment system. The reverse osmosis unit must be preceded by pre-treatment devices, and may need to be followed by post-treatment devices as well, to meet current AAMI/ANSI and FDA recognized U.S. standards.

1.7 Substantial Equivalence Comparison

1.7.1 Technological Characteristics

The fundamental scientific technology/operating principle of a software-controlled, fully automatic RO system which uses pretreated soft water to produce highly deionized water of the proposed device is substantially equivalent to the cleared AquaC UNO H device (K143617). Both the proposed and predicate devices are components of a complete water purification system and have the same key performance specifications. They must be preceded by water pretreatment devices.

The only difference between the two (2) systems is that the predicate device uses peroxide cross-linked silicone tubing while the proposed device uses platinum cross-linked silicone tubing.

1.8 Performance Data

Performance testing, including biocompatibility, Electrical Safety, EMC, bench testing, and software validation and verification was conducted for the AquaC UNO H. Results of performance testing support the substantial equivalence, safety, and efficacy of the AquaC UNO H.

1.8.1 Biocompatibility Testing

Biocompatibility testing on the AquaC UNO H was conducted in accordance with ISO 10993-1:2018 and FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process" (04 September 2020). The following endpoints were evaluated to support the biological safety of the AquaC UNO H:

- Chemical Characterization – Simulated Use (Volatiles, Semi-Volatiles, Non-Volatiles, and Trace Elements)
- Toxicological Risk Assessment of the system toxicity, genotoxicity, and carcinogenicity endpoints
- Cytotoxicity
- Sensitization
- Irritation
- Material-Mediated Pyrogenicity
- Hemocompatibility

1.8.2 Human Factors Testing

No changes to usability were made so no human factors testing was required for the silicone tubing change.

1.8.3 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety testing was performed in accordance with ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

Electromagnetic compatibility testing was performed in accordance with IEC 60601-1-2 Edition 4.1 2020-09, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic disturbances - Requirements and tests.

1.8.4 Software Verification and Validation Testing

The software is a modification to the predicate AquaC UNO H software (K143617). Individual test strategies were developed and implemented for each new or modified feature. A final inspection protocol was completed on AquaC UNO H software version 3.22.1 to verify that the device meets its specifications.

Software verification information within this submission is provided in accordance with the following FDA guidance documents:

- *Content of Premarket Submissions for Device Software Functions* (14 June 2023)
- *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (27 September 2023)
- *Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act* (13 March 2024)

1.8.5 Bench Testing

Testing to ISO 23500-1:2019, Preparation and quality management of fluids for haemodialysis and related therapies was conducted to support the determination of substantial equivalence.

Based on the review of the test results, the performance of the AquaC UNO H is acceptable. The AquaC UNO H is safe and effective for its intended use.

1.8.6 Animal Studies

No animal studies were required for the change.

1.8.7 Clinical Studies

No clinical studies were required for the change.

1.9 Conclusion

The information provided in this Traditional 510(k) demonstrates the AquaC UNO H system functions as intended and supports the determination of substantial equivalence to the predicate device. Test results demonstrate that the differences between the proposed and the predicate device do not raise any new concerns with regard to safety or effectiveness.

The Indications for Use, technological characteristics, design, and performance requirements of the AquaC UNO H system are substantially equivalent to those of the predicate device. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the AquaC UNO H system is safe and effective for its intended use.