September 9, 2025

Fresenius Medical Care North America
Greg Calder
Senior Director
920 Winter Street
Waltham, MA 02451

Re: K252181
Trade/Device Name: AquaA
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water Purification System For Hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: July 11, 2025
Received: July 11, 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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252181 |

Please provide the device trade name(s).

AquaA

Please provide your Indications for Use below.

AquaA
The AquaA water purification system is a modular 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. 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/IS0 and Federal (U.S.) standards.

Visual LED Indicator
The Visual LED Indicator is used to remotely monitor the operating status of a connected device (e.g., the reverse osmosis water treatment system).

AquaDETECTOR (Optional)
The AquaDETECTOR leakage monitoring system provides full leakage monitoring of a dialysis center, typically during non-treatment hours. The central control unit can be programed to switch off dialysis water supply systems, dialysis concentrate preparation systems, dialysis concentrate supply systems, booster pump assemblies, and pre-filtration devices when a leak is detected.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

# 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 |
| **Address:** | 920 Winter Street<br>Waltham, MA<br>02451-1457 |
| **Phone:** | (781) 467-9145 |
| **Fax:** | (781) 699-4067 |
| **Contact Person:** | Greg Calder, Senior Director |
| **Preparation Date:** | 25 Aug 2025 |

## 1.2. Device Name

| | |
|---|---|
| **Trade Name:** | AquaA |
| **Common Name:** | Subsystem, Water Purification |
| **Regulation Name:** | Water purification system for hemodialysis |
| **Regulatory Class:** | Class II per CFR § 876.5665 |
| **Product Code:** | FIP |
| **Product Code Name:** | Subsystem, Water Purification |
| **FDA Review Panel:** | Gastroenterology/Urology |

## 1.3. Legally Marketed Predicate Device

The legally marketed predicate device is the AquaA cleared under K213507. This predicate has not been subject to a design-related recall.

## 1.4. Device Description

The AquaA system is a software controlled electromechanical device. It is a reverse osmosis (RO) water purification system that uses pretreated soft water to produce dialysis water for hemodialysis (HD) devices and for the preparation of dialysis concentrates.

The AquaA system is a modular system consisting of a base module that can be used on its own or in conjunction with other modules. AquaA is the base module. AquaA2 is a second RO unit that can be added to increase the quality of dialysis water. AquaHT is a flow heater unit that can be added to provide heat disinfection for the RO system including membranes and ring main. The AquaHT module can also supply hot product water to connected HD devices. AquaUF is an ultrafiltration module for the AquaA system intended to improve dialysis water quality by retaining constituents such as endotoxins and bacteria.

### 1.4.1. Device Identification

The AquaA system is configured by combining the different modules with the AquaA base module. The system configurations are:

- AquaA (Single stage RO system)
- AquaA + AquaUF (Single stage RO system with ultrafiltration)
- AquaA + AquaHT (Single stage RO system with heat disinfection)
- AquaA + AquaHT + AquaUF (Single stage RO system with heat disinfection and ultrafiltration)
- AquaA + AquaA2 (Double stage RO system)
- AquaA + AquaA2 +AquaUF (Double stage RO system with ultrafiltration)
- AquaA + AquaA2 + AquaHT (Double stage RO system with heat disinfection)
- AquaA + AquaA2 + AquaHT + AquaUF (Double stage RO system with heat disinfection and ultrafiltration)

The Visual LED Indicator, Aqua DETECTOR, and Connecting Tube PVDF are accessories to the AquaA system.

The Visual LED Indicator is a required accessory installed in the dialysis clinic. It reproduces the AquaA's visual indicator color signals in the clinic and communicates the AquaA system's operating status (including visual and audible alarm states) to the user.

The AquaDETECTOR system monitors leakage throughout a dialysis center. The AquaDETECTOR system consists of a monitoring control center and up to 40 leakage sensors connected to 1–3 BUS lines.

The Connecting Tube PVDF is used to connect the fluid path of the installed modules while maintaining placeholders for future modular expansion.

### 1.4.2. Environment of Use

The AquaA system is intended to be operated in hospitals and clinics and will be installed in dedicated water treatment equipment rooms that are physically separated from the dialysis treatment areas. The Visual LED Indicator is installed in the dialysis treatment area.

### 1.4.3. Brief Written Description of the Device

The AquaA water purification system uses pretreated soft water to produce dialysis water for HD devices and for the preparation of dialysis concentrates. The system features the following main operating modes:

- STANDBY – The system is on and dialysis water is not being produced
- SUPPLY – The system produces dialysis water, controls the programmed yield, and monitors all relevant parameters

- RINSE – The system is cleaned with water by rinsing all tubing sections and by replacing the specified dialysis water volume
- CLEANING – The cleaning mode is used to decalcify or alkaline clean the RO system including membranes. (NOTE: The water distribution system is not included.) An acidic or alkaline solution is circulated in the system for a programmed time period. A Disinfection phase is initiated and followed by a Rinse phase.
- DISINFECTION – The system, including the ring main, is chemically disinfected. The disinfectant is circulated throughout the system for a programmed time period and then a Rinse phase is initiated.
- HEAT DISINFECTION – The AquaA system with the AquaHT module allows for heat disinfection of the AquaA system including RO membranes, ring main, and HD device interfaces
- EMERGENCY OPERATION – In the event of a system malfunction if emergency mode is initiated, AquaA or AquaA2, depending on which RO module failed, begins emergency operation as a single stage RO system. Dialysis water is still produced to complete any HD therapy that is in progress. Dialysis water conductivity (AquaA and AquaA2) and temperature (AquaA) are monitored.

### 1.4.4. Materials of Use

AquaA is classified as externally communicating, blood path indirect, permanent contact (> 30 days) duration, Class II (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 the media* include:

- PP-H polypropylene
- PSU polysulfone
- 1.4571/AISI 316 Ti stainless steel
- 1.4401/AISI 316 stainless steel
- 1.4404 stainless steel
- PVDF polyvinylidene fluoride
- EPDM ethylene propylene diene monomer
- 1.4310/AISI 301 stainless steel
- PPO polyphenylene oxide
- PS-S polystyrene
- PTFE (Teflon)
- PPSU polyphenylsulfone
- PSU polysulfone
- PA polyamide
- Borosilicate glass 3.3
- Al2O3 96% Ceramics
- 3.7165 Titanium
- 1.4539/AISI 904L stainless steel
- Sapphire
- PES polyethersulfone
- FPM fluoro rubber
- 1.4408 stainless steel
- silicone
- Polyoxymethylene
- PVC polyvinylchloride
- Silicone Carbide
- NdFeB Magnet (in epoxy resin)
- Brass nickel plate alloy

*The media includes both dialysis and concentrate water.

## 1.5. Intended Use

The AquaA device is intended for the purification of water to be used for hemodialysis.

## 1.6. Indications for Use

AquaA

*The AquaA water purification system is a modular 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. 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/ISO and Federal (U.S.) standards.*

Visual LED Indicator

*The Visual LED Indicator is used to remotely monitor the operating status of a connected device (e.g., the reverse osmosis water treatment system).*

AquaDETECTOR (Optional)

*The AquaDETECTOR leakage monitoring system provides full leakage monitoring of a dialysis center, typically during non-treatment hours. The central control unit can be programed to switch off dialysis water supply systems, dialysis concentrate preparation systems, dialysis concentrate supply systems, booster pump assemblies, and pre-filtration devices when a leak is detected.*

## 1.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the AquaA system are substantially equivalent to the predicate device AquaA (K213507):

- Intended Use
- Indications for Use
- Design Specifications
- Technological Characteristics
- Principle of Operation
- Performance Requirements

The proposed device differs from the predicate device as follows:

- Hardware changes including increased motor protection switch and power contactor spacing, increased power contactor switching current rating, and increased wire gauge for motor protection switch to power contactor connectors.
- Material change including platinum catalyzed silicone tubing for disinfectant connection and fluid fly loop.

Verification testing was performed to verify the safety and effectiveness of the proposed device for its intended use. Differences between the predicate and proposed device do not raise any questions of safety or effectiveness.

## 1.8. Performance Data

Performance testing was conducted for the AquaA. Results of the performance testing support the substantial equivalence, safety, and effectiveness of the AquaA.

### 1.8.1. Biocompatibility Testing

Biocompatibility testing 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 AquaA system:

- Cytotoxicity
- Sensitization
- Irritation
- Pyrogenicity (Material Mediated)
- Hemocompatibility
- Chemical Characterization – Simulated Use (Volatiles, Semi-Volatiles, Non-Volatiles, and Trace Elements)
- Toxicological Risk Assessment

### 1.8.2. Human Factors Validation Testing

The changes to the AquaA do not impact the usability of the device. Human Factors Validation Testing is not required.

### 1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the predicate AquaA device. The changes to the AquaA do not impact the electrical safety or EMC of the device. Electrical safety and EMC testing were not required.

### 1.8.4. Software Verification and Validation Testing

There were no changes to the AquaA software. Software verification and validation are not required.

### 1.8.5. Animal Studies

No animal studies were conducted.

### 1.8.6. Clinical Studies

No clinical studies were conducted.

## 1.9. Conclusion

The intended use, design, principle of operation, and technological characteristics of the AquaA are substantially equivalent to those of the predicate device. Differences between the AquaA and the predicate do not raise new concerns with regard to safety or efficacy. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the AquaA is safe and effective for its intended use.