July 27, 2022

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Senior Director, Regulatory Affairs
920 Winter Street
Waltham, Massachusetts 02451

Re: K213507
Trade/Device Name: AquaA
Regulation Number: 21 CFR 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: June 24, 2022
Received: June 27, 2022

Dear Denise Oppermann:

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 and Part 809); 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,

Gema Gonzalez
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213507

Device Name
AquaA

Indications for Use *(Describe)*
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.

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.

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5. 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.

5.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 996-9103
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director
Preparation Date:	29 October 2021

5.2. 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

5.3. Legally Marketed Predicate Device

The legally marketed predicate device is the AquaBplus cleared under K133829. This predicate has not been subject to a design-related recall.

The proposed device includes an optional ultrafiltration module – AquaUF – which improves the quality of dialysis water by removing retained biological contaminates from the dialysis water. The TQM TQE-H Endotoxin Filter (K161304) was selected as a reference device because, like AquaUF, it is installed after the RO system and removes biological contaminates from the dialysis water.

5.4. Device Description

The AquaA system 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.

5.4.1. 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.

5.4.2. 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.

5.4.3. 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.

5.4.4. 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 dialysis water are detailed in Table 1.

Table 1: Materials in Contact with Dialysis Water

Module	Materials
AquaA, AquaA2, AquaHT	Polypropylene Stainless steel Polyvinylidene fluoride Ethylene propylene diene monomer Polyphenylene oxide Polystyrene Polytetrafluoroethylene Polyphenylsulfone Polysulfone Polyamide Borosilicate glass Aluminum oxide ceramics Titanium Sapphire Polyethersulfone
AquaUF	Polyethersulfone Polysulfone Polyvinylidene fluoride Polypropylene Stainless steel Ethylene propylene diene monomer Fluoro-rubber Polyphenylsulfone Polytetrafluoroethylene

5.5. Intended Use

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

5.6. 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.

5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the AquaA system are substantially equivalent to the predicate device AquaBplus (K133829):

- Intended Use
- Indications for Use
- Fundamental Scientific Technology/Operating Principle
- Technological Characteristics
- Essential Performance Requirements

5.8. Performance Data

Testing conducted to support the determination of substantial equivalence for the AquaA system is summarized in Table 2.

Table 2: Performance Testing Summary

Test Conducted	Test Method Description
Essential Performance	Testing to demonstrate that the device meets the following standards: • ISO 13959 Third Edition 2014-04-01 – Water for haemodialysis and related therapies • ISO 26722:2014 – Water treatment equipment for haemodialysis applications and related therapies
Disinfection Validation	Validation of chemical and heat disinfection labeling in accordance with FDA guidance document, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff* (17 March 2015)
Functional Verification	Complete system testing to verify the performance (e.g., conductivity and temperature) and functional (e.g., operating modes and generated alarms) requirements of the device

Test Conducted	Test Method Description
Packaging	Packaging and transport verification according to ASTM D4169-16

5.8.1. 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:

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

5.8.2. Human Factors Validation Testing

Human Factors Validation Testing was not conducted. The safe and effective use of the AquaA system for its intended use with the intended users in the intended use environment was demonstrated through a comparative analysis with the predicate AquaBplus (K133829) and AquaA system marketed outside the United States.

5.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

5.8.3.1. AquaA System and Visual LED Indicator

Electrical safety testing for the AquaA system with the Visual LED Indicator was conducted in accordance with ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and *A2:2010/(R)2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)*.

Electromagnetic compatibility (EMC) for the AquaA system and the Visual LED Indicator was tested in accordance with *IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*.

5.8.3.2. AquaDETECTOR

Electrical safety testing for the AquaDETECTOR was conducted in accordance with *IEC 61010-1:2010 (3rd Edition), Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*.

EMC testing was conducted to demonstrate that the AquaDETECTOR's intended use and essential performance are maintained based on the requirements and procedures of the following standards:

- IEC 61326-1:2012, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
- FCC, Part 15, Subpart B, Class A

5.8.4. Software Verification and Validation Testing

System software verification testing was performed to demonstrate the effectiveness of the software and to confirm operation of the device. Software verification information within this submission is provided in accordance with the following FDA guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (11 May 2005)
- Guidance for Off-The-Shelf Software Use in Medical Devices (27 September 2019)
- Content of Premarket Submissions for Management of Cybersecurity in Medical device (02 October 2014)
- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (14 January 2005)

5.8.5. Animal Studies

No animal studies were conducted.

5.8.6. Clinical Studies

No clinical studies were conducted.

5.9. Conclusion

The information provided in this Traditional 510(k), including design verification, risk management, electrical safety, electromagnetic compatibility (EMC), and biocompatibility, demonstrates the AquaA 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 AquaA 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 AquaA system is safe and effective for its intended use.