June 13, 2024

Fresenius Medical Care Renal Therapies Group, LLC
Greg Calder
Senior Director, Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Re: K232953
Trade/Device Name: AquaBplus; AquaB LITE
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: May 15, 2024
Received: May 15, 2024

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232953

Device Name
AquaBplus
AquaB LITE

Indications for Use *(Describe)*

AquaBplus

The AquaBplus 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.

AquaB LITE

The AquaB LITE 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.

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 (FMCRTG)
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 467-9145
Fax:	(781) 699-9635
Contact Person:	Greg Calder, Senior Director
Preparation Date:	17 May 2024

1.2. Device Name

Trade Name:	AquaBplus, AquaB LITE
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 AquaBplus cleared under K133829. This predicate has not been subject to a design-related recall.

1.4. Device Description

The AquaBplus and AquaB LITE are reverse osmosis (RO) water purification systems that use pretreated soft water to produce dialysis water for hemodialysis (HD) devices and for the preparation of dialysis concentrates.

The AquaBplus system is a modular system consisting of a base module that can be used on its own or in conjunction with other modules. AquaBplus is the base module. AquaBplus B2 is a second RO unit that can be added to increase the quality of dialysis water. AquaBplus HF is a flow heater unit that can be added to provide heat disinfection for the RingMain. The AquaBplus HF module can also supply hot product water to connected HD devices.

The AquaB LITE system is a basic version of the AquaBplus system. Like the AquaBplus, it is a modular system consisting of a base module that can be used on its own or in conjunction with other modules. AquaB LITE is the base module and B2 LITE is a second RO unit that can be

added to increase the quality of dialysis water. AquaBplus HF is a flow heater unit that can be added to provide heat disinfection for the RingMain. The AquaBplus HF module can also supply hot product water to connected HD devices.

The differences between the predicate AquaBplus and the proposed AquaB LITE are summarized in Table 1.

Table 1: Differences Between Systems

Feature	AquaBplus System (predicate)	AquaB LITE System (proposed)
Housing Covers	Standard	No Housing Covers
Housing Concentrate Throttle	Standard	Eliminated
AquaBplus HF	Option	Requires Update-Kit-HF with RingBase plus
RingBase Basic[1]	N/A	Optional
RingBase plus[1]	Standard	Requires Update-Kit-HF
RingUnit	Option with 1 Dialysis Water Distribution Loop (DWDL) Standard with > 1 DWDL	Option with 1 DWDL RingUnit or RingUnit Basic required with > 1 DWDL
RingUnit Basic	N/A	Option with 1 DWDL RingUnit or RingUnit Basic required with > 1 DWDL
Ethernet/IT network connection	Standard	Optional
Concentrate Pressure Measurement	Sensor	Analog Manometer
Return Water Pipe DWDL to Break Tank	Stainless steel	Plastic

[1] The RingBase Basic has a mechanism for blocking dialysis water before it is fed into the dialysis water distribution system. The RingBase plus includes additional valves that allow the AquaBplus HF to be connected. The RingBase plus also allows the water coming from the dialysis water distribution system to be routed directly to the drain.

1.4.1. Device Identification

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

- AquaBplus (Single stage RO system)
- AquaBplus + AquaBplus HF (Single stage RO system with heat disinfection of RingMain)
- AquaBplus + AquaBplus B2 (Double stage RO system)

- AquaB + AquaBplus B2 + AquaBplus HF (Double stage RO system with heat disinfection of RingMain)

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

- AquaB LITE (Single stage RO system)
- AquaB LITE + AquaBplus HF (Single stage RO system with heat disinfection of RingMain)
- AquaB LITE + B2 LITE (Double stage RO system)
- AquaB LITE + B2 LITE + AquaBplus HF (Double stage RO system with heat disinfection of RingMain)

1.4.2. Environment of Use

The AquaBplus and AquaB LITE systems are intended to be operated in hospitals and clinics and will be installed in dedicated water treatment equipment rooms.

1.4.3. Brief Written Description of the Device

The AquaBplus and AquaB LITE water purification systems use pretreated soft water to produce dialysis water for HD devices and for the preparation of dialysis concentrates. The systems feature 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
- DISINFECTION – The system, including the DWDL, is chemically disinfected. The disinfectant is circulated throughout the system for a programmed period of time and then a Rinse phase is initiated.
- CLEANING – The system is chemically cleaned. The cleaning can be a decalcification or a high pH cleaning. (NOTE: The dialysis water distribution loop (DWDL) is not included in this operating mode).
- HEAT DISINFECTION – The DWDL is heat disinfected. The hot product water is circulated throughout the AquaBplus HF, RingBase, and RingMain for a programmed period of time and then a Rinse phase is initiated.
- EMERGENCY OPERATION – If emergency mode is initiated due to a system malfunction, AquaBplus/AquaB LITE or AquaBplus B2/B2 LITE (depending which RO module failed) begins emergency operation as a single stage RO system. The system continues to produce dialysis water to complete any HD therapy in progress. Dialysis water conductivity and temperature are monitored.

1.4.4. Materials of Use

AquaBplus and AquaB LITE are classified as externally communicating, blood path indirect, permanent contact (> 30 days) duration, Class II (Category C) devices 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).

The AquaBplus and AquaB LITE have the same materials in contact with the dialysis water. These materials are listed in Table 2.

Table 2: Materials in Contact with Dialysis Water

Module	Materials
AquaBplus AquaBplus B2 AquaBplus HF AquaB LITE B2 LITE	Polypropylene Stainless steel Polyvinylidene fluoride Ethylene propylene diene monomer Silicone Polyphenylene oxide Polystyrene Polytetrafluoroethylene Polyphenylsulfone Polysulfone Polyamide Polyethylene Polyoxymethylene Polyvinylchloride Brass nickel-plate alloy Aluminum oxide ceramic Titanium

1.5. Intended Use

The AquaBplus and AquaB LITE are intended for the purification of water to be used for hemodialysis.

1.6. Indications for Use

AquaBplus

The AquaBplus 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.

AquaB LITE

The AquaB LITE 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.

1.7. Comparison of Technological Characteristics with the Predicate Device

The production of highly deionized water through RO for use in hemodialysis and related therapies is the technological principle for the subject and predicate devices. The subject and predicate devices are based on the following same technological elements and operating principles:

- Microcontroller-controlled fully automatic RO systems
- Interface Specifications
- Operating Modes (Standby, Supply, Rinse, Cleaning, Disinfection, Emergency Operation, Heat Disinfection)
- Emergency Mode
- Intended Use
- Essential Performance Requirements

There are no technological differences between the proposed AquaBplus and predicate device (K133829).

The following technological differences exist between the subject AquaB LITE and predicate device (K133829):

- No housing or throttle concentrate cover on the AquaB LITE
- Use of different material in the dialysis water return pipe
- Use of different concentrate pressure measurement mechanisms

1.8. Performance Data

Testing conducted to support the determination of substantial equivalence for the AquaBplus and AquaB LITE system is summarized in Table 3.

Table 1: Performance Testing Summary

Test Conducted	Test Method Description
Essential Performance	Testing to demonstrate that the device meets the following standards: • *ISO 23500-1 First Edition 2019-02, Preparation and quality management of fluids for haemodialysis and related therapies – Part 1: General requirements* • *ISO 23500-2 First Edition 2019-02, Preparation and quality management of fluids for haemodialysis and related therapies – Part 2: Water treatment equipment for haemodialysis applications and related therapies* • *ISO 23500-3 First Edition 2019-02, Preparation and quality management of fluids for haemodialysis and related therapies – Part 3: Water for haemodialysis and related therapies*
Software	*IEC 62304 Edition 1.1 2015-06 (Consolidated Version), Medical device software – Software life cycle processes*
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
Packaging	Packaging and transport verification according to ASTM D4169-16

1.8.1. Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993-1:2020 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 AquaBplus and AquaB LITE systems:

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

1.8.2. Human Factors Validation Testing

Human Factors Validation Testing was not conducted. None of the modifications for the proposed devices involved critical tasks for the clinical user. A review of post-production information for the predicate device did not identify new use-related risks. The AquaBplus and AquaB LITE systems are safe and effective for their intended use with the intended users in the intended use environment.

1.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety testing 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 (Consolidated Text), Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*. Testing was conducted using a worst-case scenario device and the results apply to both the AquaBplus and AquaB LITE systems.

Electromagnetic compatibility (EMC) was conducted in accordance with *IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*. Testing was conducted using a worst-case scenario device and the results apply to both the AquaBplus and AquaB LITE systems.

1.8.4. Software Verification and Validation Testing

System software verification testing was performed to demonstrate the effectiveness of the software and to confirm the operation of the device. Software verification information within this submission is provided in accordance with *IEC 62304 Edition 1.1 2015-06 Consolidated Version Medical Device Software – Software Life Cycle Processes* and the following FDA guidance documents:

- *Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff* (14 June 2023)
- *Off-The-Shelf Software Use in Medical Devices, Guidance for Industry and Food and Drug Administration Staff* (11 August 2023)
- *Draft Guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* (18 October 2018)
- *Draft Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (8 April 2022)
- *Guidance for Networked Medical Devices Containing Off-the-Shelf (OTS) Software* (14 January 2005)
- *Guidance for Postmarket Management of Cybersecurity in Medical Devices* (27 December 2016)

1.8.5. Animal Studies

No animal studies were conducted.

1.8.6. Clinical Studies

No clinical studies were conducted.

1.9. Conclusion

The information provided in this Traditional 510(k), including design verification, risk management, electrical safety, electromagnetic compatibility (EMC), and biocompatibility demonstrates the proposed AquaBplus and AquaB LITE systems function as intended and supports the determination of substantial equivalence to the predicate device (K133829). Test results demonstrate that the differences between the proposed and the predicate devices do not raise any new concerns regarding safety or effectiveness.

The Indications for Use, technological characteristics, design, and performance requirements of the AquaBplus and AquaB LITE systems are substantially equivalent to those of the predicate device. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the AquaBplus and AquaB LITE systems are safe and effective for their intended use.