August 16, 2023

B. Braun Medical Inc.
Rushtin Chaklader
Regulatory Affairs Specialist
901 Marcon Blvd
Allentown, Pennsylvania 18109

Re: K223479
Trade/Device Name: AQUAbase nX, AQUAbase nX HT
Regulation Number: 21 CFR 876.5665
Regulation Name: Water Purification System for Hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: July 14, 2023
Received: July 17, 2023

Dear Rushtin Chaklader:

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); 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, MS
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)*

K223479

Device Name
AQUAbase nX

Indications for Use *(Describe)*

The AQUAbase nX is intended for use with hemodialysis systems to remove organic and inorganic substances and microbial contaminants from the water used for treating hemodialysis patients. The AQUAbase nX is to be used at dialysis clinics or hospitals

The AQUAbase nX is a reverse osmosis unit intended to be a component in a complete water purification system, and is not a complete water treatment system. This reverse osmosis unit must be preceded by pre-treatment devices. Whether a particular device is included in an individual water treatment system will be dictated by local conditions. The reverse osmosis unit may need to be followed by post-treatment devices as well.

The AQUAbase nX is designed to meet current AAMI/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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

complying with 21 CFR 807.92

AQUAbase nX

I. APPLICANT AND SUBMITTER

Applicant
B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen, Germany
Establishment Registration Number: 3007007791

Submitter
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
610-266-0500

Contact
Rushtin Chaklader
Regulatory Affairs Specialist
Phone: (610) 596-2789
E-mail: rushtin.chaklader@bbraunusa.com

Date prepared: 11/08/2022

II. DEVICE

Name of device:	**AQUAbase nX**
Classification name:	Water Purification System for Hemodialysis (21 CFR 876.5665)
Regulatory class:	II
Product code:	FIP
Product code name:	Subsystem, Water Purification
FDA Review Panel:	Gastroenterology/Urology

III. PREDICATE DEVICE

Aquaboss (Eco)RO Dia I + II (HT)
510(k) number: K124059

IV. DEVICE DESCRIPTION

The AQUAbase nX is a single stage reverse osmosis system. A graphical touchscreen allows access and monitoring of all operating parameters at any time. Customized parameters make a high water yield possible, even under poor raw water conditions. Raw water consumption is based solely on the end user's permeate needs. The touchscreen makes it possible for the user to monitor all production parameters as well as design every system function, including disinfection mode, individually and reproducibly.

Operating principle

The AQUAbase nX works on the reverse osmosis principle. Reverse osmosis describes the process of pressure-operated cross-filtration. Water flows at high pressure tangentially over a semipermeable membrane. As is the case with normal filtration, the system is cleaned by allowing one component (water) of the mixture to be separated to pass through the membrane with almost no hindrance, while other components (dissolved and undissolved water contents) are held back to a greater or lesser extent and leave the filtration unit in the concentrate flow. This is a purely physical separation process in the molecular range which does not change the components being separated either chemically, biologically or thermally.

Following models are available:

Single pass / Single staged Chemical disinfection		Flow rate of dialysis water (permeate) in l/h (gph) @ 10°C (50°F)	
		L/h @ 10°C	gph @ 50°F
	AQUAbase® nX 300	300 L/h	79 gph
	AQUAbase® nX 600	600 L/h	158 gph
	AQUAbase® nX 900	900 L/h	237 gph
Single pass / Single staged Heat disinfection			
	AQUAbase® nX HT 250	250 L/h	66 gph
	AQUAbase® nX HT 500	500 L/h	132 gph
	AQUAbase® nX HT 750	750 L/h	198 gph

Device characteristics

The system has the following design features:

- Disconnection from mains/free water intake
- User-friendly touchscreen control

- Password protection of configurable device data
- Compact design
- Low power consumption
- Single pipe construction
  - The single pipe construction ensures easy servicing of the membrane. The membrane pipe is made of stainless steel.
- AQUAbase nX HT hot water-disinfectable, full-fit elements
  - All hot-cleanable reverse osmosis systems in the AQUAbase nX HT series come with special full-fit reverse osmosis membrane elements whose external, high precision-manufactured, knurled polypropylene texture makes them especially suitable for use in microbially sensitive water treatment systems.
- Low dead-space, stainless steel piping
  - The entire system is designed to achieve the lowest possible dead-space. High flow rate and the resulting shear forces also significantly reduce the risk of biofilm growth on the pipe walls.

V. INTENDED USE AND INDICATIONS FOR USE

Intended Use:
Device that is intended for use with a hemodialysis system to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate.

Indications for Use:
The AQUAbase nX is intended for use with hemodialysis systems to remove organic and inorganic substances and microbial contaminants from the water used for treating hemodialysis patients.
The AQUAbase nX is to be used at dialysis clinics or hospitals

The AQUAbase nX is a reverse osmosis unit intended to be a component in a complete water purification system, and is not a complete water treatment system.
This reverse osmosis unit must be preceded by pre-treatment devices. Whether a particular
device is included in an individual water treatment system will be dictated by local conditions.
The reverse osmosis unit may need to be followed by post-treatment devices as well.

The AQUAbase nX is designed to meet current AAMI/ISO and Federal (U.S.) standards.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparing the subject device to the predicate device, some similarities and differences are noted in the design employed to accomplish the same intended use:
Both systems utilize reverse osmosis for purification of water to be used for Hemodialysis. Product water complies with the international standard ISO 23500-3, as recognized by FDA.
The subject and predicate devices are based on the following same technological elements:

- Both utilize a polyamide, thin film composite, and spiral wound membrane.
- Both are modular system families.
- Similar sensors and same general setup of the cabinet
- Both shall be installed and commissioned by B. Braun certified technicians and shall be operated by trained personnel.
- Both systems shall undergo annual technical inspections
- Optional heat disinfection available for both
- Use of substantially equivalent water contact materials in both systems
- Chemical disinfection using peracetic acid disinfection products or heat disinfection possible for both
- Both display poor water quality and pressure alarms
- Both monitor water quality on digital displays

The following differences exist between the subject and predicate devices:

- Differences in indications for use, based on the scope of the predicate device submission (system including pre-treatment, reverse osmosis and post-treatment). The subject device is compared to the reverse osmosis subset of the predicate device only.
- User interface of the subject device and predicate device is different.
- The predicate device offers a back washing option (“Eco”) which is not offered in the subject device.
- Difference in water conversion control (volume controlled in the predicate device and conductivity controlled in the subject device)
- Systems differ in output specification. The subject device provides output range for smaller clinics whereas the predicate device provides output range for bigger clinics.
- Predicate device is available as an option as double staged system. Subject device is available as single staged system.
- Optional heat disinfection is available for both. Heater option for optional heat disinfection is integrated in the subject device. The predicate device must be linked to a separate inline hot cleaning system.

- Remote alarm monitoring system available in the predicate device. Acoustic alarms available in the subject device.
- Difference in the supervision of the controller function (via watchdog in the predicate device and observer system in the subject device).
- Emergency operation mode available in the predicate device for the optional double staged system. Not required in the subject device being a single staged system.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the AQUAbase nX was conducted in accordance with the international standard ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", as recognized by FDA.
The battery of testing included the following tests:

- cytotoxicity
- hemolysis
- chemical characterization (leach test)

The AQUAbase nX has indirect blood contact with the patient and contact duration is less than 24 hours for one single treatment and long term for cumulative use.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the AQUAbase nX. The system complies with the IEC 60601-1 standard for electrical safety and with IEC 60601-1-2 standard for EMC.

Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" as well as the draft FDA guidance recently issued.

Additional performance bench testing conducted on the device include:

- performance testing according to the international standard ISO 23500-3, as recognized by FDA
- chemical and heat disinfection testing
- bacterial count and endotoxins

VIII. CONCLUSIONS

The conclusions drawn from the nonclinical bench tests demonstrate that the AQUAbase nX is as safe, as effective and performs as well as than the legally marketed device identified in section III.
Testing results indicate that the device complies with all requirements stated in applicable recognized consensus standards for water purification systems for hemodialysis.
The device has equivalent technical features and intended use as the predicate device and the differences between the two do not introduce new issues of safety and effectiveness.
The AQUAbase nX is therefore considered substantially equivalent to the predicate device.