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JUL 5 2012

"Section 4: 510(k) Summary"

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and 21 CFR 807.92

Section 4.1: Contact Information:

Address:	Arion Water, Inc. 1 Commerce Way Bldg #1 – Unit C Carver, MA 02330
Applicant:	Robert Livingston - President
Telephone:	508-465-2280
Fax:	508-465-2283

Contact:	Robert Livingston Chief Technical Officer
Telephone:	508-465-2280 x114
E-mail:	bob@arionwater.com
Date Prepared:	08/11/2011

Bob Livingston will respond to any requests for additional information.

Section 4.2: Intend to Market Device Information

Device Name:	Arion Dialysis Water System
Common Name:	High Purity Water System.

Trade Name (Model #): (P10BYD, P15BYD, P20BYD, RO50A, RO100A, RO300A, RO300ALP, RO500A, RO1000A, RO1000ALP, RO1500A, RO2000A, HPW125PP, HPW150PP, HPW200PP, HPW125SS, HPW150SS, HPW200SS) See Section 10: Device Description for details.

Classification Name:	Water System for Hemodialysis
Classification Panel:	21 CFR 876.5665
Product Code:	78FIP

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Section 4.3: Predicate Device Information

Identification of Predicate Devices:

Section 4.3.1: Predicate Device #1:

Company:	Biolab Equipment Canada Limited
510(k) Number:	K030348
Common Name:	Reverse Osmosis systems with pretreatment and product water distribution components
Trade Name (Model #):	Biopure Portable RO Systems Biopure 4400 Series RO Systems Biopure 8400 Series RO Systems

Biopure Water Purification Pretreatment Componets:

Softeners:

- Biopure Performa Softener
- Biopure Magnum Series Water Softener

Backwash Filters:

- Biopure Performa Filter
- Biopure Magnum Series Carbon Filter
- Biopure Magnum Series Carbon Filter
- Biopure Magnum Series Multimedia Filter

Service Deionization:

- Biopure Service DI
- Biopure Premium Grade Service
- Biopure Cation Bed DI
- Biopure Anion Bed DI
- Biopure Auto DI

Organic Bed Service Carbon:

- Biopure Carbon

Biopure Product Water Distribution Components:

- Biopure CIP System
- Biopure Hot Water Sanitization System

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Classification Name:
Water Purification System for Hemodialysis
Regulatory Classification – Class II
21 CFR 876.5665

Product Code: 78 FIP

Classification Panel: 21 CFR 876.5665

Section 4.3.2: Predicate Device #2:

Company: Performance Water Systems, LCC

510(k) Number: K033648

Common Name: Complete Water Treatment System with pre-treatment and product water distribution.

Trade Name (Model #): Performance Water Treatment System

Classification Name:
Water Purification System for Hemodialysis
Regulatory Classification – Class II
21 CFR 876.5665
Class II Critical Medical
Device

Product Code: 78 FIP

Classification Panel: 21 CFR 876.5665

Section 4.4: Intend to Market Device Description:
The Arion Dialysis Water System is comprised of water purification equipment used to purify water for hemodialysis.

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Section 4.5: Indications for Use:

The Arion Dialysis Water System is for use in multi-patient hemodialysis. The system consists of pretreatment, reverse osmosis, post-treatment and distribution equipment. The sizing of the system is consisting with the demand of water needed for patients. The water produced will meet the minimum requirements of ANSI/AAMI American National Standard for Water Treatment Equipment for Hemodialysis Applications (RD52:2004 and RD62:2006/A1:2009) and the CMS End Stage Renal Disease (ESRD) Program Interpretive Guidance (based on 42 CFR 494) when used as directed. RO and Pretreatment design is based off of feed water quality to meet the stated specifications. This system is intended to be used in hospitals, dialysis centers, and dialysis clinics.

Section 4.6: Comparison to Predicate Device:

The Arion Dialysis Water System is substantially equivalent to many marketed devices that are used in Hemodialysis. Table 4.6.1 compares systems for the companies of Arion Water, Inc., Performance Water Systems, LCC, and Biolab Equipment Canada Limited.

The system listed use RO as a primary purification method. The system design must be similar to the Arion Dialysis Water System due to the regulations of ANSI/AAMI RD62:2006. The standard states certain requirements for the design of water treatment system for Hemodialysis.

The Arion Dialysis Water System provides safe mechanical and electrical operations. The electrical components are enclosed with in a NEMA enclosure in compliance with building and electrical codes. The Arion Water Dialysis system has no exposed moving parts.

Chemicals being used in water treatment are often monitored with pH probes and other sensors. The Arion Dialysis Water System has no pH probe because it does not use chemicals. The only time the system would need chemicals in during sanitization. When sanitization is in progress test strips and/or metering devices are used to ensure correct amounts of chemicals are used. All chemicals used in the sanitization of the dialysis system are certified by the EPA or conform to AAMI standards.

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Table 4.6.1: Comparison of Hemodialysis Equipment

Description	**Arion Water, Inc.**	**Performance Water Systems, LCC**	**Biolab Equipment Canada Limited**
Pretreatment	Multimedia, Dual Carbon, Softener	Dual Carbon	Multimedia, Dual Caron, Softner
RO	Primary Purification	Primary Purification	Available
Distribution	Standard	Available	Standard
Intended Use	Hemodialysis	Hemodialysis	Hemodialysis
Indications of Use	Complete System: Pretreatment, RO, Distribution	Complete System: Pretreatment, RO, Distribution	Complete System: Pretreatment, RO, Distribution
Target Population	People who use Dialyzers	People who use Dialyzers	People who use Dialyzers
Materials	Polypropylene Distribution Loop/ SS Option AAMI Compliant Materials	AAMI Compliant Materials	AAMI Compliant Materials
Location of Use	Hospitals	Hospitals	Hospitals
Performance Standards	AAMI RD62	AAMI RD62	AAMI RD62
Sterilized	Monthly	Monthly	Monthly

Section 4.7: Non-clinical Performance Data:

A water treatment system must be tested for water quality at the time of install. If the system can't produce water quality specified in ANSI/AAMI RD52:2004, then it can't be used for hemodialysis. Each system will be tested and not be operational until it is shown that the water quality meets AAMI standards. The system will be tested for chemical containments on a quarterly basis.

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Section 4.8: Clinical Performance Data:

This system is not required to have Clinical Test performed.

Section 4.9: Conclusion of Performance Data:

The Arion Dialysis Water System is capable of meeting ANSI/AAMI standards by producing water that has chemical containments below the maximum acceptable levels. The system is designed to conform to ANSI/AAMI equipment and design regulations. If the water does not meet quality, the system will be sanitized and retested. Equipment should be shown to operating properly. If the system can still not meet quality, the system will be decommissioned.

Section 4.10: Statement of Water Quality:

|----------Beginning of Statement----------|

Arion Water certifies that the water produced by each customized purification system will meet or exceed current industry standards and government regulations.

ROBERT LIVINGSTON
Print Name

Sign Name

20 JUN 12
Date

|----------End of Statement----------|

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert Livingston
Chief Technical Officer (CTO)
Arion Water, Inc.
1 Commerce Way Bldg. 1 Unit C
CARVER MA 02330

JUL 5 2012

Re: K112331
Trade/Device Name: Arion Dialysis Water System
Regulation Number: 21 CFR§ 876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: June 21, 2012
Received: July 2, 2012

Dear Mr. Livingston:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112331

Device Name: Arion Dialysis Water System

Indications For Use:

The Arion Dialysis Water System is for use in multi-patient hemodialysis. The system consists of pretreatment, reverse osmosis, post-treatment and distribution equipment. The sizing of the system is consisting with the demand of water needed for patients. The water produced will meet the minimum requirements of ANSI/AAMI American National Standard for Water Treatment Equipment for Hemodialysis Applications (RD52:2004 and RD62:2006/A1:2009) and the CMS End Stage Renal Disease (ESRD) Program Interpretive Guidance (based on 42 CFR 494) when used as directed. RO and Pretreatment design is based off of feed water quality to meet the stated specifications. This system is intended to be used in hospitals, dialysis centers, and dialysis clinics.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112331