NOV 1 8 2005

510(K) SUMMARY
510(K) Number : K051620

1 Date Prepared
August 26, 2005

2 Contact Person
Mike Cline
President, Better Water, Incorporated
698 Swan Drive
Smyrna, TN 37167
615-355-6063

3 Device Name

Proprietary Name:	Matrix Series Digital Reverse Osmosis Water Treatment System
Common Name:	Reverse Osmosis Water Purification System For Hemodialysis with Digital Controls
Panel:	Gastroenterology/Urology
Classification Name:	Water Purification System For Hemodialysis; Class II; Water purification system for hemodialysis (21 CFR 876.5665); Product Code 78 FIP

4 Device Description

The Matrix Series Digital Reverse Osmosis Water Treatment System is an accessory device that is intended for use with a hemodialysis applications and is intended to remove organic and inorganic substances and microbial contaminants from tap water used to dilute dialysate concentrate to form dialysate. The Matrix Series Digital Reverse Osmosis Water Treatment System will produce water as prescribed by the Association for the Advancement of Medical Instrumentation (AAMI) RD62:2003 standard provided adequate flow rate of the feed (tap) water and compliance with existing drinking water standards and proper pre-treatment.

5 Substantial Equivalence To Predicate Device

The Matrix Series Digital Reverse Osmosis Water Treatment System is based upon the technology of the *Water Purification System For Hemodialysis* manufacturered by Better Water (K920186) with respect to "wetted-contact materials", pump size and the selection of the type and number of membranes.

Additionally, the Matrix Series features an electronic PLC with firmware as well as an Operator Interface Touch Screen. These electronic features are equivalent to the electronic features incorporated in the MD 400 (K993200) and 600 (K041163) Series Water Systems manufactured by Isopure Incorporated.

See the table below for detailed comparison.

Table of Comparison To Predicate Devices

Specifications	Matrix Current 510(K)	Predicate Devices		
		Water Purification System For Hemodialysis	Complete Water System Models MD 610, 620, 630 and 640	Multi-Patient Reverse Osmosis - Models MD 420, 440, 460, 470, 480 and 490
Manufacturer	Better Water, Inc	Better Water, Inc	Isopure Corporation	Isopure Corporation
510(K) Number	-	K920186	K041163	K993200
Decision Date	-	6/13/1995	10/7/2004	1/24/2000
Classification	876.5665, Class II	876.5665, Class II	876.5665, Class II	876.5665, Class II
Product Code	FIP	FIP	FIP	78 FIP
Water-Contact Materials	FDA - NSFCompliant	FDA - NSFCompliant	FDA - NSFCompliant	FDA - NSFCompliant
Pre-Treatment Options	Based upon site-specific feed water chemical analysis.	Based upon site-specific feed water chemical analysis.	Based upon site-specific feed water chemical analysis.	Based upon site-specific feed water chemical analysis.
	Feed water Pre-Treatment may include	Feed water Pre-Treatment may include :	Feed water Pre-Treatment may include :	Feed water Pre-Treatment may include :
	• Carbon Filtration	• Carbon Filtration	• Carbon Filtration	• Carbon Filtration
	• Softners	• Softners	• Softners	• Softners
	• Temperature Control	• Temperature Control	• Temperature Control	• Temperature Control
	• Pressure Compensation	• Pressure Compensation	• Pressure Compensation	• Pressure Compensation
	• Special Filtration	• Special Filtration	• Special Filtration	• Special Filtration
	• Ultra-Violet (UV)	• Ultra-Violet (UV)	NA	NA
	• Ozone	NA	NA	NA
Operational Features	Electronic touch screen interface	Manual Controls	Electronic touch screen interface	Electronic touch screen interface
	All components mounted on an open frame for assessibility	All components mounted on an open frame for assessibility	All components mounted on an open frame for assessibility	All components mounted on an open frame for assessibility
	Electronic Monitoring of	Analog Monitoring of	Electronic Pressure Monitoring of	Electronic Pressure Monitoring of
	• Feed water pressure / flow	• Feed water pressure	• Feed water pressure	• Feed water pressure
	• Product water pressure/ flow	• Product water pressure	• Product water pressure	• Product water pressure
	• Membrane feed pressure	• Membrane feed pressure	• Membrane feed pressure	• Membrane feed pressure
	• Pump Pressure	• Pump Pressure	• Pump Pressure	• Pump Pressure
	• Reject Water Pressure/Flow	• Reject Water Pressure/Flow	• Reject Water Pressure/Flow	• Reject Water Pressure/Flow
	• Product Water Conductivity	• Product Water Conductivity	• Product Water Conductivity	• Product Water Conductivity
	• Feed water Conductivity	• Feed water Conductivity	• Feed water Conductivity	• Feed water Conductivity
	• System Flush	• Manual	• System Flush	• System Flush
	• Clean/Disinfect Flow Rate	• NA	• Semi-Automated	• Semi-Automated

Table of Comparison To Predicate Devices cont'

Cleaning	Manual or Automated System cleaning and sanitizing by: • chemicals agents	Not Applicable	Manual or Automated System cleaning and sanitizing by: • chemical agents	Manual or Automated System cleaning and sanitizing by: • chemical agents
Safety Features	100% diversion-to-drain above product conductivity set-point	100% diversion-to-drain above product conductivity set-point	100% diversion-to-drain above product conductivity set-point	Not Applicable
	Low Supply (Feedwater) Pressure (Alarm)	Low Supply (Feedwater) Pressure (Alarm)	Low Supply (Feedwater) Pressure (Alarm)	Low Supply (Feedwater) Pressure (Alarm)
	High Product Water Conductivity (alarm)	High Product Water Conductivity (shut down)	High Product Water Conductivity (shut down)	High Product Water Conductivity (shut down)
	High supply water temperature (shut down)	High supply water temperature (shut down)	High supply water temperature (shut down)	High supply water temperature (shut down)
	High product water conductivity alarm	High product water conductivity alarm	High product water conductivity alarm	High product water conductivity alarm
	System Recovery Notification	Not Applicable	System Recovery Notification	System Recovery Notification
	Power Disturbance (Alarm)	Power Disturbance (Alarm)	Power Disturbance (Alarm)	Power Disturbance (Alarm)
	Remote Alarm (Nurse's Station)	Remote Alarm (Nurse's Station)	Remote Alarm (Nurse's Station)	Remote Alarm (Nurse's Station)
Post-Treatment Options	May include 0.5 micron or better ultra-filtration	May include 0.5 micron or better ultra-filtration	May include 0.5 micron or better ultra-filtration	May include 0.5 micron or better ultra-filtration
Performance	Delivery of AAMI Standard Water	Delivery of AAMI Standard Water	Delivery of AAMI Standard Water	Delivery of AAMI Standard Water

6 Indications For Use

The Matrix Series Digital Reverse Osmosis Water Treatment System is an accessory device designed to safely and effectively provide water purification for use in hemodialysis applications. The water produced will meet the minimum water quality requirements as specified by Association for the Advancement of Medical Instrumentation (AAMI) standard RD62:2003 when used as directed. Dependent on feed water quality this unit **may** be used in conjunction with other approved water treatment components.

7 Safety and Effectiveness

The intended use and technological characteristics of the Matrix Series Digital Reverse Osmosis Water Treatment System are similar or equivalent to the Predicate Devices. Any difference between the device and the Predicate Devices have no significant influence on the safety or effectiveness of the product.

8 Clinical Performance Data

Not required for determination of substantial equivalence for this type and class of device.

9 Conclusion Drawn From Clinical and Nonclinical Test Data

As compared with the predicate devices, K920186, K993200 and K041163, the Matrix Series Digital Reverse Osmosis Water Treatment System will produce purified water that will meet the minimum water quality requirements as specified by Association for the Advancement of Medical Instrumentation (AAMI) standard RD62:2003 when used as directed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2005

Mr. Michael Cline
President
Better Water, Inc.
698 Swan Drive
SMYRNA TN 37167

Re: K051620
Trade/Device Name: Matrix Digital Reverse Osmosis Water Treatment System – EQRMD Series
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: November 16, 2005
Received: November 17, 2005

Dear Mr. Cline:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

510(K) Number : **K051620**

Device Name : Matrix Series Digital Reverse Osmosis Water Treatment System

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____
(Division Sign-Off)

_____
Title

_____
Date

510(K) Number : **K051620**

Prescription Use ✓ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

David G. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051620