BJJ&A
Total Water Treatment
Bob J. Johnson & Associates, Inc.

K014169

FEB 0 6 2002

San Antonio Office
7715 Mainland
Suite 115
San Antonio, Texas 78250
(210) 684-7638
(210) 681-1339 Fax

Corporate Office
1313 FM 1960 E.
Houston, Texas 77073
(281) 443-2225
(281) 443-6831 Fax

Dallas Office
2619 Farrington Street
[illegible]as, Texas 75207
[illegible]) 631-4316
(214) 631-4657 Fax

San Angelo Office
7433 Billo Dr.
San Angelo, Tx. 76901
(915)482-2202

Lubbock Office
516 84th Street
Lubbock, Texas 79404
(806) 745-7933
(806) 745-8631 Fax

Harlingen Office
Federico Vaquera
(956)778-2099
(956)642-3355 Fax

PREMARKET NOTIFICATION 510(k) SUMMARY

November 30, 2001

Bob J. Johnson & Assoc., Inc.
7715 Mainland Dr. #115
San Antonio, Texas 78250
Robert Snyder

Ph: (210)684-7638
Fax: (210)681-1339

WATER PURIFICATION COMPONENTS FOR HEMODIALYSIS
Regulatory Classification:
Class II
CFR 876.5665(a)

Product Code:
78 FIP

Note: In this summary the word "component" refers to an individual part of a water treatment system. Example : the water softener or the carbon filter. The word system refers to the water purification plant as a whole. Example: the water softener, carbon filter, reverse osmosis, storage tank, ultrafiltration, ultraviolet sterilizer, and pumping systems. We are claiming substantial equivance to components

Bob J. Johnson & Assoc., Inc. (BJJ&A) is applying for a 510(k) premarket notification for our "Water Purification Components for Hemodialysis". The following is a summary of our submission document. The regulatory classification is class II CFR 876.5665(a), Product Code 78 FIP. The device we are claiming substantial equivalence to is marketed by U.S. Filter. The registration number for this device is K980182, U.S. Filter Water. Purification System. Regulatory Class: II, 21 CFR 876.5665/Procode: 78 FIP.

The BJJ&A water purification system for hemodialysis will be used with a hemodialysis system. The Water purification system will remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate, bicarbonate, acetate and sterilant for dialyzer reprocessing.

The purified water will also be used in the equipment disinfection process, equipment rinsing and any other application the clinic/customer deems appropriate. This system will meet all the requirements put forth by the United States Food and Drug Administration (FDA) and the Association for the Advancement of Medical Instrumentation (AAMI) and any other laws that may apply.

The BJJ&A water purification components utilize no new water purification techniques, carbon filtration and water softening. The predicate device system we are claiming SE to, utilizes the exact same water purification principles. The following is a comparison summary of the BJJ&A water treatment components and the predicate device.

BJJ&A and U.S. Filter both utilize a water softener made of materials, which are "NSF" and/or FDA approved. U.S. Filters' softener is installed with a single regeneration tank and electrically interlocked to shut down the RO unit operation during the softener regeneration cycle. BJJ&A softeners are installed in a single regeneration tank configuration such as USF or in a duplex-twin alternating fashion to provide softened water to the system 24 hours a day. While one regeneration tank is in a regeneration cycle the other regeneration tank is on line providing soft water to the system. This will prevent the possibility of softener regeneration or a salt dump into the water purification system during a patient shift. This also eliminates the need to shut down the RO unit for softener regeneration. Information is available in the "purposes and operation" summary.

Carbon filtration is utilized by both BJJ&A and U.S. Filter to filter out chlorine and chloramines from the water, BJJ&A uses carbon filter made from materials, which are FDA or NSF approved. Both companies use two carbon filters in a series configuration with test ports installed after each filter. A minimum total contact time of 10 empty bed contact time minutes are incorporated into both designs as recommended by the FDA for chlorine and chloramine removal. Both BJJ&A and U.S. Filter recommended the chlorine and chloramine levels be checked before each patient shift. Hard plumbed bypass piping of the carbon tanks is not allowed on either component. Both components will utilize an activated carbon with an Iodine number of 900 or greater. Both BJJ&A and U.S. Filter uses in line carbon regeneration filters. U.S. Filter uses a single carbon filter in its single patient dialysis system. BJJ&A always uses a dual carbon filter in series in every dialysis water system installed, including single patient systems.

BJJ&A and U.S. Filter incorporate emergency equipment bypass lines and valving that are clearly labeled and tagged. Instructions for usage will be included with the water components and staff in-service will be provided to the clinic/customer by BJJ&A. The use of dead legged bypass piping will be avoided. Carbon filters will not have hard plumbed bypass lines. U.S. Filter emergency equipment bypass utilizes a dry bypass technique. This method uses breakable unions and isolation valves at the end of each bypass line so that stagnant water will not be present in the line in the event of an emergency bypass condition. BJJ&A emergency equipment bypass is a wt bypass method.

In this method the bypass valve is installed with no more than one half pipe a diameter length on either side of the bypass valve to avoid water stagnation. The use of dead leg bypass piping is unacceptable.

BJJ&A water distribution piping will be configured with no dead legs longer than 6 pipe diameters. U.S. Filter installs sanitization/sanitant introduction valve(s) or introduction port must be incorporated to allow chemical injection of sanitants to allow sanitization of the RO system and storage tanks and the deionization connections or through the top of the storage tank. By suing one of these two sites for sanitant introduction BJJ&A avoids having any additional deadleg bypass valving installed into the original piping system and this further avoids water stagnation.

Included in this document is labeling that is applied to the components of the water purification system for hemodialysis. AAMI water purification standards are also included

With an actual water quality analysis and Total Organic Carbon analysis from existing water purification components for dialysis. Dimensional drawings and product specification sheets are included in this submittal along with owner's manuals for each of the components models.

In summary, the BJJ&A water purification components and the U.S. Filter predicate device components are very similar to one another. The core water purification components and technology are exactly the same. The differences are in the application of the bypass equipment. Most of the differences in these two systems are derived from the fact BJJ&A is in a constant attempt to provide the best water quality and safest possible system to the public.

Note: The Renal Care Facilities will supply their own reverse osmosis system, ultra-filtration rack, DI, and storage tanks. BJJ&A will only be providing the water softener systems and carbon systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

Mr. Robert Snyder
Regional Manager, South Texas Territory
Bob J. Johnson & Assoc., Inc.
7715 Mainland Dr., #115
SAN ANTONIO TX 78250

Re: K014169
Trade/Device Name: Water Purification Components for Hemodialysis
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: November 30, 2001
Received: December 19, 2001

Dear Mr. Snyder:

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 (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); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

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

K014169

Carbon Filters and Water Softeners are intended to be used as components of a water purification system to remove organic and inorganic substances from water that is used to dilute dialysis concentrate to form dialysate and to produce purified water for other purposes such as dialyzer reprocessing and equipment rinse and disinfection

BOB J. JOHNSON & ASSOCIATES, INC.
1313 FM 1960 E.
HOUSTON, TX 77073
281-443-2225
1-800-341-2225

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014169