K071104
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Flier's Quality Water Systems inc

JAN 14 2008

510(k) Summary

This 510(k) Summary is provided as part of this Premarket Notification to comply with the provisions of the safe Medical Devices Act of 1990 requiring that either a summary be included in a submission or a statement that a summary is available upon request.

Submitter
James B. Flier
Flier's Quality Water Systems, Inc.
7425 Clyde Park Ave. SW
Byron Center, MI 49315
April 13, 2006

Device Names
Acute System #1, Acute System #2 (AS-1, AS-2)
Central System #1, Central System #2 (CS-1, CS-2)
Back-up System #1, Back-up System #2 (BS-1, BS-2)

Common or usual name
Deionization system with pre & post treatment and water distribution components.

Classification name
Water purification systems for hemodialysis (21CFR 876.5665)

Predicate Device

The Flier's Quality Water Systems, Inc. systems are substantially equivalent to USFilter Corporation's/Siemens (K980182) predicate marketed water treatment systems for dialysis which use carbon and deionization canisters with pre and post filtration to purify water for hemodialysis.

Device Description

The systems are primary or temporary devices used to provide water for hemodialysis applications per the requirements of ANSI/AAMI RD62:2001.

The Flier's Quality Water Systems, Inc. systems purify potable feed water through deionization. Deionization is used to remove 99.9% of ions from water. Deionization alone does not remove particulates, organics, bacteria, viruses or endotoxins. The systems require pretreatment and post-treatment. Deionizers are designed in a hemodialysis application to treat RO water or carbon filtered potable water. Improper use can result in the formation of nitrosamines in the effluent of the deionizer.

The purpose of the pretreatment section of the system is to condition that feed water supplying the deionizers. Conditioning the feed water will include: cartridge filters to reduce particulates and sediment and carbon filtration tanks to remove chlorine/chloramine residual.

The purpose of the post-treatment section of the system is to remove bacteria and endotoxins or lower them to acceptable levels as required by AAMI standards. The post-treatment section of the system will include: submicron/ultrafilters after the deionizers, sample ports to check for microbial contamination and to test for comprehensive AAMI analysis, a 1 megohm quality control light at mid tank and a temperature compensated audible and visual resistivity alarm set at 1M ohm or greater for final water quality. A remote alarm will be installed if the deionization system is not located in the patient treatment area. A distribution section of the system is necessary to deliver product water that meets ANSI/AAMI standards to the points of use. During use, continual monitoring of the effluent through the use of the temperature compensated audible and visual resistivity alarm is required. Routine monitoring of the mid tank quality indicator is also required on intervals during the day, at least before and after each patient treatment.

Should final water quality fall at or below 1 megohm, the alarm will sound and all patient treatments must be discontinued. The deionization tanks must be replaced per tank exchange procedure prior to resuming and patient treatment.

Divert to drain option will be provided when necessary per AAMI guidelines. Divert to drain is not supplied for acute systems located in patient room. Monitor and divert to drain not supplied for back-up systems with existing monitor/alarm/divert.

Indications for Use

The Acute System #1 consists of two each carbon and mixed bed DI tanks with pre & post filtration. It is intended to be placed on the back of dialysis machine or on a handcart for single patient dialysis. Acute System #2 consists of just carbon tanks and is intended to be used as pretreatment to a single patient RO system.

The Central System #1 and #2 consists of two or more carbon and mixed bed DI tanks with pre & post filtration. They are used as either a temporary system to feed multiple dialysis machines in normal use, or for a system to feed a biomedical technician service station. For permanent, multiple station dialysis clinics Flier's recommends using central water treatment systems including reverse osmosis.

The Back-up System #1 and #2 consists of two or more mixed bed DI tanks as a component in a "back up" condition when a RO system or major component on a water purification system for hemodialysis is in need of repair. It may also be used in DI polishing mode to remove ions from an RO stream to meet AAMI RD62:2001 requirements.

Conclusion

In both the case of Flier's systems and the predicate device carbon filtration is utilized to filter out chlorine and chloramines from the water. Both companies use two carbon filters in a series configuration. A minimum empty bed contact time of 10 minutes is incorporated into the designs as recommended by the FDA for chlorine and chloramine removal. Both companies utilize an

activated carbon with an Iodine number of 900 or greater. Flier's always recommends installing dual carbon tanks in series including single patient systems (Acute System #1, Acute System #2).

In both cases deionization tanks are utilized to remove dissolved solids from the water. Both utilize mixed bed resin, consisting of anion and cation resin, to remove the charged particles from the water. Both utilize parts and materials which are NSF and/or FDA approved.

In summary, the components of Flier's systems and those of the US Filter/Siemens predicate device are very similar to one another. The core water purification components and technology are exactly the same. The predicate device components utilize the exact same water purification principles..

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2008

Mr. James Flier
Quality Committee
Flier's Quality Water Systems, Inc.
7425 Clyde Park Ave., S.W., Suite A
BYRON CENTER MI 49315

Re: K071104
Trade/Device Name: Acute Portable Exchange Deionization (PEDI) System
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: December 26, 2007
Received: December 26, 2007

Dear Mr. Flier:

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 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Flier's Quality Water Systems inc

Indications for Use

510(k) Number: K071104

Device Name: Acute System #1, Acute System #2 (AS-1, AS-2)
Central System #1, Central System #2 (CS-1, CS-2)
Back-up System #1, Back-up System #2 (BS-1, BS-2)

Indications for Use:

Flier's Quality Water Systems, Inc. systems are primary or temporary devices to provide water for hemodialysis applications per the requirements of ANSI/AAMI RD62:2001. They remove organic and inorganic substances and microbial contaminants from water used to dilute dialysis concentrate to form dialysate, in the reprocessing of hemodialyzers, and equipment rinse and disinfection.

The Acute System #1 consists of two each carbon and mixed bed DI tanks with pre & post filtration. It is intended to be placed on the back of dialysis machine or on a handcart for single patient dialysis. Acute System #2 consists of just carbon tanks and is intended to be used as pretreatment to a single patient RO system.

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Upon exhaustion, these tanks will be replaced with other tanks containing newly regenerated resin, or with new resin altogether.

These systems are components of a larger water treatment system employing adequate pre-treatment and post-treatment sections. Flier's systems are not to be used alone.

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, Abdominal,
and Radiological Devices
510(k) Number K071104