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
Raymond Kowalec
Simply Clean Air & Water
FDA Establishment No. 3004114902
28 Shepard Drive
P.O. Box 310962
Newington, CT 06131-0962
Tel: (860) 231-0687
Fax:(860) 231-1425
March 4, 2005

Device Names
Acute Portable Exchange Deionization (PEDI) System
Central PEDI System
Back-up PEDI System

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 Simply Clean Air & Water PEDI Systems are substantially equivalent to US Filter Corporation's (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 PEDI systems are primary or temporary devices to provide water for hemodialysis applications per the requirements of ANSI/AAMI RD62:2001 .

The systems consist of a booster pump / pressure tank assembly, sediment filter, carbon filtration, mixed bed deionizers, resin trap filter, endotoxin filter and system monitoring with flow isolation/divert and remote alarm functions. Refer to Operating Manuals for flow diagrams.

The booster pump / pressure tank assembly (central system only) consists of a multistage pump, pressure tank and pressure switch. The multistage pump construction has minimum 304 SST wetted

parts with no copper or iron wetted parts. The pressure (bladder) tank construction is an airtight shell of cold rolled steel with a FDA approved butyl rubber diaphragm to separate water from tank inside and air charge. The booster pump / pressure tank operates using 115V/1P/60Hz power to operate a multistage pump to raise pressure up to 80 psig.

The sediment filter consists of a polypropylene housing with pressure relief valve and a replaceable filter cartridge. The filter cartridge consists of spun polypropylene fiber wound on a polypropylene core and with a filtration rating of 10 microns. (Back-up system uses existing sediment filtration).

The carbon filtration consists of ABS lined fiberglass pressure tank containing granular activated carbon and PVC distributors. The size and number of tanks is dependent on flowrate required with maximum values listed in Appendix C. Back-up system uses facilities existing carbon filters if available, Acute system single tank.

The mixed bed deionizers consist of ABS lined fiberglass pressure tank with PVC distributors containing mixed bed ion exchange resin. The size and number of tanks is dependent on flowrate required and inlet water conductivity maximum values listed in Operating Manual.

The resin trap filter consists of a polypropylene housing with pressure relief valve and a replaceable filter cartridge. The filter cartridge consists of spun polypropylene fiber wound on a polypropylene core and has a filtration rating of 5 microns. (Not used on acute systems).

The endotoxin filter consists of a polypropylene housing with a replaceable filter cartridge. The filter cartridge consists of an element with 222 o-ring/closed type seals and has a reduction factor of 10^7 for bacteria and 10^3 for endotoxins.

System monitoring consists of pressure gauges, quality control indicator and resistivity monitor. Pressure gauges prior to deionization minimum brass body with phosphorous bellows, gauge after deionization 304 SST stem with SST bellows. The resistivity monitor has a digital readout, indicators for above and below water quality, push buttons for alarm setpoint indication and alarm function test. Connections to the monitor provide under low water quality: remote alarm (horn), isolation of flow to use (valve) and diversion of flow to drain (valve). Inline sensor construction stainless element with polypropylene body. Divert to drain 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. Refer to Operating Manuals for Control Diagram.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

Mr. Raymond Kowalec
Simply Clean Air & Water
28 Shepard Drive
P.O. Box 310962
NEWINGTON CT 06131-0962

Re: K042018
Trade/Device Name: Acute PEDI System, Central PEDI System, and Back-up PEDI System
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: March 4, 2005
Received: March 22, 2005

Dear Mr. Kowalec:

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.

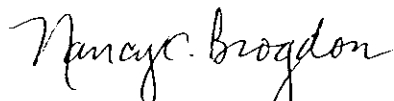
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

510(k) Number (if known): K042018

Device Name: Acute PEDI System
Central PEDI System
Back-up PEDI System

Indications For Use:

Systems are intended for use with a hemodialysis system to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysis concentrate to form dialysate, reprocessing of hemodialyzers, equipment rinse and disinfection.

The Acute PEDI System consists of a sediment filter, carbon filtration, mixed bed deionizers, endotoxin filter and system monitoring with remote alarm functions. It is intended for use in a location with a portable dialysis machine for the dialysis of a single patient.

The Central PEDI System consists of a booster pump / pressure tank assembly, sediment filter, carbon filtration, mixed bed deionizers, resin trap filter, endotoxin filter and system monitoring with flow isolation/divert and remote alarm functions. It is intended for use in a central location for the dialysis of multiple patients.

The Back-up PEDI System consists of mixed bed deionizers, intermediate water quality (QC) indicator (light) and connection hoses. It is intended for use to provide a "back-up" for reverse osmosis unit repair or to "polish" the product outlet of a RO to meet AAMI RD62:2001 requirements. Endotoxin filtration and system monitoring with flow isolation / divert and remote alarm functions are provided when required to meet ANSI/AAMI RD62:2001 requirements.

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 K042018