MAY 28 2003

Summary of Safety and Effectiveness Information

The following information is furnished in accordance with 21 CFR 807.92(a):

1. **Submitter's name and address:**

   Purity Water Company
   1119 Paulsun
   San Antonio, Texas, 78219-3182

2. **Submitter's telephone number:**

   (210 227-3601

3. **Contact person:**

   Mr. Bill Herrera

4. **Date this 510(k) summary prepared:** May 28, 2003

5. **Trade/proprietary name of the device:**

   Water Purification System for Dialysis

6. **Classification name of the device:**

   Water purification system for dialysis

7. **Legally marketed predicate device to which substantial equivalence is claimed:**

   Better Water, Inc. Water Purification System for Hemodialysis

8. **Description of the device that is the subject of this premarket notification:**

   Water purification system for hemodialysis.

Summary of Safety and Effectiveness Information

9. Indications for use:

- *Purify water used in hemodialysis treatment in dialysis centers/facilities having multiple treatment stations.*
- *Purify water used in hemodialysis treatment in hospital intensive care units, critical care units, pediatric intensive care units, and other acute care applications within a hospital setting.*

10. Technological characteristics:

The typical customized system is configured with booster pump, multimedia filtration, water softener, carbon filter, reverse osmosis, storage tank, ultra-filtration, deionization tanks, audible and visual alarms, and other components that purify water as a function of feed water quality and required capacity. The system product water complies with the AAMI Standard RD62:2001, *Water Treatment Equipment for Hemodialysis Applications.*

510(k) Summaries for those submissions in which a determination of substantial equivalence is also based on performance data shall also contain the following information in accordance with 21 CFR 807.92(b):

11. Non-clinical: Brief discussion of the non-clinical tests submitted, referenced, or relied upon in this submission:

Following the installation of the water purification system a sample of the product water produced by the system is taken and analyzed by an independent laboratory to determine the level of contaminants in the water. These laboratory results are compared with the maximum permitted level for each contaminant in order to determine that the product water purified by the system meets the customer's requirements for purified water. This method was also used by the predicate device to demonstrate compliance with recognized acceptable contaminant levels in product water.

Summary of Safety and Effectiveness Information

The performance test results of the candidate device complied with the requirements of:

- AAMI Standard RD62:2001, *Water Treatment Equipment for Hemodialysis Applications*
- USP: Total Organic Carbon

12. Clinical:

There are no clinical tests submitted, referenced, or relied upon in this submission.

..... END .....

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2003

Purity Water Company
c/o Mr. Bert Hudson
President
Hudson Consulting, Inc.
803 Evian
SAN ANTONIO TX 78258

Re: K022448
Trade/Device Name: Purity Water Company Water Purification System
Regulation Number: 21 CFR §876.5665
Regulation Name: Water purification system for hemodialysis
Regulatory Class: II
Product Code: 78 FIP
Dated: February 25, 2003
Received: February 27, 2003

Dear Mr. Hudson:

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

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

Enclosure

510(k) number (if known): K022448

Device name: Water purification system

Indications for use of the device:

Purify water for hemodialysis treatment in dialysis centers/facilities having multiple treatment stations.

Purify water for hemodialysis treatment in hospital intensive care units, critical care units, pediatric intensive care units, and other acute care applications within a hospital setting.

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CBER, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use
(Per 21 CFR 801.109)

(Optional format 1-2-96)

David G. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022448