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Appendix C

**Water Purification System
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:*
Water & Power Technologies of Texas, Inc.
2125 109th Street
Grand Prairie
Texas 75050
2. *Submitter's telephone number and fax number:*
Tel: (972) 988 0583
Fax: (972) 602 3119
3. *Contact person:*
Mr. Tim Manley
4. *Date this 510(k) summary prepared:*
December 20, 1999
5. *Trade/proprietary name of the device:*
Water Purification System
6. *Classification name of the device:*
Water Purification System for Hemodialysis
7. *Legally marketed predicate device to which substantial equivalence is claimed:*
Mar Cor Services, Inc. Complete Water Treatment System for Kidney Dialysis (Ref. K945559)
8. *Description of the device that is the subject of this premarket notification:*
The WPT Water purification System has been developed around the Osmonics 23G Reverse Osmosis machine and the use of deionizer exchange tanks to demineralize the feed water.
The feed water passes through three separate stages in the purification process before the required quality of product water is achieved. These stages are referred to as:

Pre-treatment using a Water Softener to remove scale forming minerals, a

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Multi-media Filter and Pre-Filter to remove suspended particulate solids and Activated Carbon Filters to remove organics e.g. chlorines and chloramines. *Primary Treatment* using a Reverse Osmosis (RO) Machine and/or Mixed Bed Deionizers (DI), both of which have already been approved by the FDA, to demineralize the water.

Post Treatment using Mixed Bed Deionizers (DI), Ultraviolet Disinfection (UV) and a Submicron Post Filter to remove suspended solids and bacteria from product water prior to distribution to the point of use.

9. *Intended use and indication for use:*

To purify water that is to be used for medical purposes

10. *Technological characteristics:*

WPT design, engineer, construct, test, and install complete water purification systems to meet specific defined and agreed customer requirements for product water quality. The primary purification is performed using the principle of Reverse Osmosis ("RO").

The water purification system takes water from the incoming supply ("feed water"), treats it through a number of system components to remove organic, inorganic and microbial contaminants, and provides purified water ("product water") to the point of use.

In order for WPT to design the system so that it is safe, efficient and functional in providing purified water to the point of use the first task is to obtain an analysis of the incoming feed water supply. This analysis, together with data regarding the incoming water flow rate and pressure, the minimum and maximum water temperatures, the operational requirements, plus the quality and volume of product water required at the point of use, is used to determine the size of the system and the combination of components required.

Depending on the requirements of the product water purity and the quality of the feed water some of the individual components of the system may be omitted without having an adverse effect on the quality of the product water supplied to the end user. However, the system will always be specified to ensure that it complies with recommended maximum chemical contaminant levels. The selection of suitable components is also governed by the intended location of the system and any restrictions applicable to its

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installation.

WPT use their experience and expertise, together with the guidelines issued by various government and industry bodies to design the appropriate system to satisfy the requirements of the customer.

The candidate device has the same technological characteristics the predicate device with both devices being designed around the same FDA approved model of Reverse Osmosis Machine. In addition both the candidate and predicate devices are designed using the same criteria regarding feed water quality, flow rate and pressure together with the customers target product water quality specification and volume requirements at the point of use.

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 present in the water. These laboratory results are compared with the maximum permitted level for each contaminant in order to determine that the water produced by the system meets the customers requirements for purified water.

This method is also used by the predicate device to demonstrate compliance with recognized acceptable contaminant levels in product water.

12. Clinical: Brief discussion of the clinical tests submitted, referenced, or relied upon in this submission:

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 2 2001

Water & Power Technologies of Texas, Inc.
c/o Mr. Barry Pearce
Shotwell & Carr, Inc.
3535 Firewheel Drive, Suite A
Flower Mound, TX 75028-2628

Re: K994292
Water Purification System
Dated: September 29, 2000
Received: October 4, 2000
Regulatory Class: II
21 CFR §876.5665/Procode: 78 FIP

Dear Mr. Pearce:

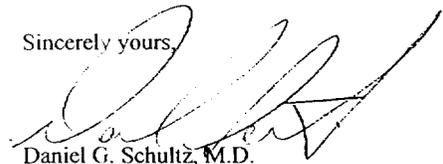
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) number (if known):

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Device name:

Water Purification System

Indications for use of the device:

The device is intended to remove organic and inorganic substances and microbial contaminants from water that is used to dilute dialysis concentrate to form dialysate and to produce purified water for dialyzer reprocessing and equipment rinse and disinfection.

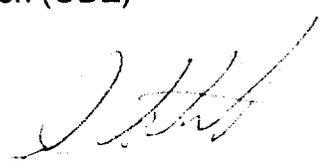
(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use or
(Per 21 CFR 801.109)

or

Over-the-Counter Use


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K994292

(Optional format 1-2-96)