SEP 23 1998

510K(k) SUMMARY

SUBMITTER: **Gambro Healthcare**
1185 Oak Street
Lakewood, CO 80215
(303) 231-4436

DATE PREPARED: **Friday, December 26, 1997**

DEVICE NAME: **Gambro Central Water Treatment System CWP 100 – WRO H**

CLASSIFICATION NAMES: **Water Purification System for Hemodialysis**

PREDICATE DEVICE: **Osmonics Osmo 23 G Series Reverse Osmosis Machines**

Device Description:

General Description

The Gambro Central Water Treatment System CWP 100 – WRO H is designed to produce water of adquate quality for hemodialysis, both chemically and microbiologically with an adequate flow, provided that the feed water complies with the existing standards for drinking water and has been properly pre-treated. The WRO or the base unit of the CWP system, operates under the principle of reverse osmosis (RO) which is the preferred method for the purificationof water for hemodialysis. This system removes at least 95% of the total dissolved salts (based on conductivity measurements) and more than 99% of the bacteria and endotoxins from the inlet water. The WRO H also include a heat disinfection unit for disinfection of the distribution system which utilizes hot water to minimize any form of microbial growth and biofilf formation. With this system, dialysis machines can be included in this heat disinfection cycle, provided that they have heat disinfection capability. This procedure is called *integrated heat disinfection.*

In order to ensure that the microbiological quality will be maintained, this system has:

- an automated disinfection procedure to keep the membrane surfaces clean and to minimize bacterial growth;
- a hygenic design with smooth surfaces and a minimum of stagnant zones;
- automatic flushing programs at preset intervals when the system is not in use

In addition, the WRO H has been designed to reduce water consumption by automatically regulating the pump speed to the actual demand of pure water.

After pretreatment (i.e. sediment filter, water softener, charcoal filter, etc.) the water enters an inlet tank (please refer to position 4 on the following diagram) via a solenoid

valve (1). The inlet water tank (4) has a float valve (5) and an air gap to help isolate the flowpath from the municipal water system. The main pump (33) then creates a pressure of up to 20 bar that is required for the reverse osmosis process.

Pure water from the WRO unit is distributed directly to the distribution system in the hemodialysis unit via solenoid valves (48), (103), and (105). Excess pure water that has not been used in the hemodialysis unit is recirculated back to the inlet water tank (4) via solenoid valve (106).

In order to reduce water consumption, the speed of the pump is automatically adjusted so that the return flow of water is kept constant. Part of the reject water is recirculated back to the sucking side of the main pump via valve (71) to help minimize water consumption and to maintain a high flow velocity over the membrane surface. The rest of the reject water is, however, continuously sent to the drain via a needle valve (41).

The WRO unit utilizes a proportioning pump (45) and solution container (46) to proportion disinfectant during the disinfection cycle. The proportioning pump is disconnected from the flow path during normal operation.

The pure water line has a solenoid valve (36) for automatic flushing to drain at the start up, in conductivity alarm situations, every two hours, when the unit is in stand-by mode and at rinse during disinfection. The pure water line also has a solenoid valve arrangement to isolate the system from the distribution system during disinfection. The WRO unit has an overflow valve (64) on the pure water side to control pressure and to relieve pressure peaks.

Conductivity Monitoring

The conductivity of the inlet water and pure water are continuously monitored by two conductivity cells (32) and(35), and are presented on the display on the operator's panel.

Flow Monitoring

The following flow rates are monitored

Flow	Sensor Position	Designation
Inlet Water	**3**	**F1**
Reject From the RO Unit	**42**	**F2**
Return Pure Water from the Clinic	**51**	**F4**

These flow rates are used to calculate the following:

- **Actual pure water consumption,**
  (F5=F1-F2)
- **Outlet pure water flow,**
  (F6=F1-F2+F4)

All flow rates are presented on the operator's panel on request.

Heat Disinfection Unit

The heat disinfection unit consists of a tank (90) made of stainless steel and an electrical heater (91). The heater maintains the temperature of the pure water in the tank at either 60 °C (Low) or 90 °C (High). Heat disinfection of the pure water distribution system is initiated by the operator at the end of the dialysis day / session. A circulation pump (96) circulates hot water in the loop until the process is interrupted either manually by the operator, or at a preset time prior to the start of the next dialysis day / session. During the disinfection period, integrated heat disinfection with the dialysis machines can also be performed if the dialysis machines have a heat disinfection capability. The tank automatically refills with pure water from the WRO unit during the next operation. Heating of the water from 60 °C (Low) to 90 °C (High) takes approximately 2.5 hours if no circulation the loop takes place. During circulation periods the required time is longer because of heat losses and varies depending on the length and design of the system.

Heating Capacity

The heat disinfection unit is capable of maintaining 85 °C in a well insulated piping system with a maximum length of 150 meters.

Predicate Devices:

The Gambro Central Water Treatment System CWP 100 – WRO H is substantially equivalent to other water purification systems for hemodialysis in commercial distribution in the United States to include the Osmonics Osmo 23 G Series Reverse Osmosis Machines (FDA Document Control Number K931595 B. Both systems utilized reverse osmosis for purification of water to be used for hemodialysis. Both systems utilize a polyamide, thin film composite, spiral wound membrane for reverse osmosis. Both systems are intended to be used for water purification for hemodialysis. Both systems utilize substantially equivalent water contact materials for pumps, tubing, and other fittings, etc. Both systems utilize software for control and alarm systems. Both systems come in a number of sizes to accommodate varying product water output requirements. Both systems can utilize chemical disinfection using peracetic acid disinfection products. The Gambro water purification system has the additional advantage of having an integrated heat disinfection capability for both the reverse osmosis system and the distribution system.

We therefore consider the Gambro Central Water Treatment System CWP 100 – WRO H to be substantially equivalent to the Osmonics Osmo 23 G Series Reverse Osmos Machines. The following table provides the necessary information on the predicate device to which this system is substantially equivalent.

PREDICATE DEVICE

DEVICE NAMES	**Osmonics Osmo 23 G Series Reverse Osmosis Machines**
INTENDED USE	**Water Purification System for Hemodialysis**
510K NUMBER	**K 931595B**
APPROVAL DATE	**1993**

Intended Use:

The Gambro Central Water Treatment System CWP 100 – WRO H is designed to produce water of adquate quality for hemodialysis, both chemically and microbiologically with an adequate flow, provided that the feed water complies with the existing standards for drinking water and has been properly pre-treated.

This indication statement is essentially the same as the indication statement for the predicate device.

Technological Characteristics:

Comparing the proposed device to the predicate device, some similarities and differences are noted in the design employed to accomplish the same intended use. Both systems utilized reverse osmosis for purification of water to be used for hemodialysis. Both systems utilize a polyamide, thin film composite, spiral wound membrane for reverse osmosis. Both systems are intended to be used for water purification for hemodialysis. Both systems utilize substantially equivalent water contact materials for pumps, tubing, and other fittings, etc. Both systems utilize software for control and alarm systems. Both systems come in a number of sizes to accommodate varying product water output requirements. Both systems can utilize chemical disinfection using peracetic acid disinfection products. The Gambro water purification system has the additional advantage of having an integrated heat disinfection capability for both the reverse osmosis system and the distribution system.

Summary of Non-Clinical Tests:

In vitro performance testing was performed on the Gambro Central Water Treatment Systems to establish normal operating performance to include flow rates, rejection of dissolved salts, organic materials, bacteria, and pyrogen. Additional testing was performed to evaluate the safety of the materials having water contact at various temperatures. The results of these tests confirmed that the proposed device is substantially equivalent to the proposed device for these parameters.

Clinical Test Results:

Clinical testing was not performed

Conclusions:

Testing performed on the Gambro Central Water Treatment System CWP 100 WRO H indicates that they are safe, effective, and perform as well as the predicate device, when used in accordance with the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1998

Jeffrey R. Shideman, Ph.D.
GAMBRO Healthcare
1185 Oak Street
Lakewood, CO 80215-4498

Re: K974899
GAMBRO Reverse Osmosis System
CWP 100-WRO-H
Dated: July 7, 1998
Received: July 13, 1998
Regulatory Class: II
21 CFR 876.5665/Procode: 78 FIP

Dear Dr. Shideman:

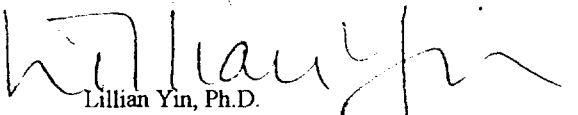
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4613. 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 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,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use:

The Gambro Central Water Treatment System CWP 100 – WRO H is designed to produce water of adquate quality for hemodialysis, both chemically and microbiologically with an adequate flow, provided that the feed water complies with the existing standards for drinking water and has been properly pre-treated.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974899/S2

Prescription Use ✓
(Per 21 CFR 801.109)